



January 1993

What Remains of the Laches and Estoppel Defenses After Aukerman?

Evan Finkel

Follow this and additional works at: <http://digitalcommons.law.scu.edu/chtlj>



Part of the [Law Commons](#)

Recommended Citation

Evan Finkel, *What Remains of the Laches and Estoppel Defenses After Aukerman?*, 9 SANTA CLARA HIGH TECH. L.J. 1 (1993).
Available at: <http://digitalcommons.law.scu.edu/chtlj/vol9/iss1/1>

This Article is brought to you for free and open access by the Journals at Santa Clara Law Digital Commons. It has been accepted for inclusion in Santa Clara High Technology Law Journal by an authorized administrator of Santa Clara Law Digital Commons. For more information, please contact sculawlibrarian@gmail.com.

ARTICLES

WHAT REMAINS OF THE LACHES AND ESTOPPEL DEFENSES AFTER *AUKERMAN*?

by Evan Finkel*

TABLE OF CONTENTS

I. BACKGROUND	3
II. GENERAL PRINCIPLES REGARDING THE LACHES AND EQUITABLE ESTOPPEL DEFENSES	4
1. <i>Laches and Estoppel are Available Under 35 U.S.C. § 282</i>	4
2. <i>Laches and Estoppel are Both Committed to the Sound Discretion of the District Court</i>	5
3. <i>Laches and Estoppel Must Both be Proven by a Preponderance of the Evidence, Not by Clear and Convincing Evidence</i>	5
4. <i>Laches Bars Only Pre-Filing Damages, While Estoppel Is a Complete Defense to a Patent Infringement Suit</i>	6
III. LACHES DEFENSE GENERALLY	6
1. <i>The Two Elements of a Laches Defense: Undue Delay & Material Prejudice</i>	6
2. <i>The Presumption of Laches</i>	17
3. <i>The Laches Presumption Shifts the "Burden of Coming Forward" With Evidence; but the "Ultimate Burden of Proof" Remains With the Accused Infringer</i>	18
4. <i>Bursting the Bubble: Rebutting the Laches Presumption</i>	20

Copyright © 1993 by Evan Finkel.

* Mr. Finkel is a member of Spensley Horn Jubas & Lubite, a law firm specializing in patent, copyright, trade secret, unfair competition, computer law, and other intellectual property matters. Mr. Finkel is the chairman of the firm's Intellectual Property Counsel Group, and is resident in the firm's Los Angeles office. He holds a J.D. from Hastings College of the Law where he was elected to the Order of the Court and the Thurston Society; and a B.S. in mathematics and computer science from S.U.N.Y. at Binghamton where he graduated with honors.

5. <i>Summary of the Laches Presumption after Aukerman; and its Impact on Future Cases</i>	20
IV. EQUITABLE ESTOPPEL DEFENSE GENERALLY	22
1. <i>The Three Elements of an Estoppel Defense</i>	22
2. <i>Don't Confuse the Second and Third Elements</i>	28
3. <i>No Presumption of Estoppel</i>	28
V. OTHER EQUITABLE CONSIDERATIONS WHICH MAY DEFEAT A LACHES DEFENSE OR AN ESTOPPEL DEFENSE, EVEN A PRESUMPTIVE LACHES DEFENSE .	29
1. <i>Copying as the Most Common Equitable Factor Defeating a Laches or Equitable Estoppel Defense</i> ..	30
2. <i>Burdens Re Copying as an Equitable Factor Defeating A Laches or Equitable Estoppel Defense on Summary Judgment</i>	33
VI. LACHES AND ESTOPPEL APPLIED TO THE AUKERMAN FACTS.....	34
VII. CONCLUSION	35

Laches and equitable estoppel are both judicially-created equitable defenses to a patent infringement action. A successful laches defense bars a patentee from recovering damages for acts of infringement occurring *at any time before the complaint was filed*. Equitable estoppel, on the other hand, is a complete defense to a patent infringement action, barring the patentee from recovering *any* damages for patent infringement and precluding the issuance of an injunction against future infringement. In *A.C. Aukerman Co. v. R.L. Chaides Construction Co.*,¹ the Federal Circuit went *en banc* to reaffirm, clarify and, in a few instances, repudiate various principles governing the application of these two important defenses.² Any prior Federal Circuit precedent inconsistent with *Aukerman* is now overruled; that is the effect of an *en banc* decision.³ Any practitioner considering application of the doctrines of laches and equitable estoppel to a given set of facts and circumstances must, therefore, fully understand the principles of law pronounced by the Federal Circuit in *Aukerman*.

I. BACKGROUND

The following facts were not disputed.⁴ Plaintiff, Aukerman, was the owner of two patents relating to a product, called a "slip-form," and a method of using that product to form concrete highway barriers.⁵ Defendant, Chaides, used a slip-form product purchased from a third party, Gomaco, to form concrete highway barriers.⁶ Between February and April 1979, Aukerman sent letters to Chaides accusing Chaides of infringing the patents, but offering Chaides a license under the patents.⁷ In April 1979 Chaides provided a written response stating (i) that any responsibility was Gomaco's, and (ii) that "if Aukerman wished to sue Chaides 'for \$200-\$300 a year,' Aukerman should do so."⁸ There was no further correspondence or contact between the parties for more than eight years, during which time Chaides increased its business of forming

1. 960 F.2d 1020, 22 USPQ2D (BNA) 1321 (Fed. Cir. 1992) (*en banc*).

2. 960 F.2d at 1028, 22 USPQ2D (BNA) at 1324 ("The court has taken this case *en banc* to clarify and apply principles of laches and equitable estoppel which have been raised as defenses in this patent infringement suit.").

3. *Newell Co.'s Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 765, 9 USPQ2D (BNA) 1417, 1423 (Fed. Cir. 1988) ("This court has adopted the rule that prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned *en banc*.").

4. *Aukerman*, 960 F.2d at 1026, 22 USPQ2D (BNA) at 1323.

5. *Aukerman*, 960 F.2d at 1026, 22 USPQ2D (BNA) at 1323.

6. *Aukerman*, 960 F.2d at 1026, 22 USPQ2D (BNA) at 1323.

7. *Aukerman*, 960 F.2d at 1026, 22 USPQ2D (BNA) at 1323.

8. *Aukerman*, 960 F.2d at 1026-27, 22 USPQ2D (BNA) at 1323.

barrier walls with slip-forms by about twenty times and began manufacturing its own allegedly infringing slip-forms.⁹ Then, in October 1987, prompted by a licensee's complaint about Chaides' substantial competition, Aukerman sent a letter to Chaides advising Chaides "that litigation against another company had been resolved, and threatening litigation unless Chaides executed a license."¹⁰ Chaides refused to enter into a license, and on October 26, 1988, Aukerman sued Chaides for infringement.¹¹

The district court held on summary judgment that Aukerman was barred under principles of laches and equitable estoppel from maintaining the suit. Aukerman appealed. On appeal, the Federal Circuit reversed, holding that the district court improvidently granted summary judgment of laches and estoppel.

II. GENERAL PRINCIPLES REGARDING THE LACHES AND EQUITABLE ESTOPPEL DEFENSES

1. *Laches and Estoppel are Available Under 35 U.S.C. § 282*¹²

The Federal Circuit rejected the patentee's argument "that the defense of laches is inapplicable, as a matter of law, against a claim for damages in patent infringement suits."¹³ Instead the Federal Circuit reaffirmed its prior holdings that "[l]aches is cognizable under 35 U.S.C. § 282 (1988) as an equitable defense to a claim for patent infringement."¹⁴ The Federal Circuit made a similar holding as to equitable estoppel, explaining that "[e]quitable estoppel is cognizable under 35 U.S.C. § 282 as an equitable defense to a claim for patent infringement."¹⁵ In this regard, it is noteworthy that the Federal Circuit explained, for the first time in any reported case of which this author is aware, that laches and equitable estoppel are "unenforceability" defenses within the meaning of 35 U.S.C. § 282(1)¹⁶ which provides in pertinent part: "The following shall be

9. *Aukerman*, 960 F.2d at 1027, 22 USPQ2D (BNA) at 1323-24.

10. *Aukerman*, 960 F.2d at 1027, 22 USPQ2D (BNA) at 1323-24.

11. *Aukerman*, 960 F.2d at 1027, 22 USPQ2D (BNA) at 1324.

12. 35 U.S.C. § 282 (1988).

13. *Aukerman*, 960 F.2d at 1028, 22 USPQ2D (BNA) at 1326.

14. *Aukerman*, 960 F.2d at 1028, 22 USPQ2D (BNA) at 1324. The Federal Circuit also stated: "Thus, we reaffirm the ruling in *Leinoff v. Louis Milona & Sons*, 726 F.2d 734, 220 USPQ 845 (Fed. Cir. 1984) and our subsequent precedent that laches is available as a defense to a suit for patent infringement." 960 F.2d at 1032, 22 USPQ2D (BNA) at 1328.

15. *Aukerman*, 960 F.2d at 1028, 22 USPQ2D (BNA) at 1325.

16. *Aukerman*, 960 F.2d at 1029, 22 USPQ2D (BNA) at 1325-26.

defenses in any action involving the validity or infringement of a patent and shall be pleaded: (1) Noninfringement, absence of liability for infringement or *unenforceability*”¹⁷

2. *Laches and Estoppel are Both Committed to the Sound Discretion of the District Court*

The Federal Circuit explained that “[a]s equitable defenses, laches and equitable estoppel are matters committed to the sound discretion of the trial judge and the trial judge’s decision is reviewed by this court under the abuse of discretion standard.”¹⁸

3. *Laches and Estoppel Must Both be Proven by a Preponderance of the Evidence, Not by Clear and Convincing Evidence*

A patent is presumed *valid* by statute.¹⁹ This presumption of validity can be overcome only by *clear and convincing* evidence.²⁰ Inequitable conduct, an affirmative defense²¹ which renders a patent *unenforceable* when the applicant for a patent intentionally makes material misrepresentations to the patent office in order to procure the patent, also must be established by *clear and convincing* evidence.²² Since laches and equitable estoppel are affirmative defenses²³ which render, to different degrees, patents *unenforceable*,²⁴ one might conclude that those defenses too must be established by *clear and convincing* evidence. However, in *Aukerman* the Federal

17. 35 U.S.C. § 282(1) (1988) (emphasis added).

18. *Aukerman*, 960 F.2d at 1028, 22 USPQ2D (BNA) at 1325.

19. 35 U.S.C. § 282.

20. *Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1459, 221 USPQ (BNA) 481, 486 (Fed. Cir. 1984).

21. *In re Innotron Diagnostics*, 800 F.2d 1077, 1078, 231 USPQ (BNA) 178, 179 (Fed. Cir. 1986).

22. *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872, 9 USPQ2D (BNA) 1384, 1389 (Fed. Cir. 1988) (*en banc*) (“Inequitable conduct resides in failure to disclose material information, or submission of false material information, with an intent to deceive, and those two elements, materiality and intent, must be proven by clear and convincing evidence.”), *cert. denied*, 490 U.S. 1067 (1989).

23. *Aukerman*, 960 F.2d at 1038, 22 USPQ2D (BNA) at 1333 (“Finally, we reiterate that, at all times, the defendant bears the ultimate burden of persuasion of the affirmative defense of laches.”); *Sig Swiss Indus. Co. v. Fres-Co. Sys. USA, Inc.*, 22 USPQ2D (BNA) 1601, 1602 (E.D. Pa. 1992) (“SIG has asserted equitable estoppel as an affirmative defense” against a claim for patent infringement).

24. *Kingsdown*, 863 F.2d at 877, 9 USPQ2D (BNA) at 1392 (“When a court has finally determined that inequitable conduct occurred in relation to one or more claims during prosecution of the patent application, the entire patent is rendered *unenforceable*. We, *en banc*, reaffirm that rule as set forth in *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1561, 223 USPQ 1089, 1093-94 (Fed. Cir. 1984).”) (emphasis added).

Circuit concluded that while it had never before addressed the issue,²⁵ laches and equitable estoppel in a patent case need only be proven by a *preponderance of the evidence*,²⁶ a much lower standard for the defendant to meet than *clear and convincing evidence*.²⁷

4. *Laches Bars Only Pre-Filing Damages, While Estoppel Is a Complete Defense to a Patent Infringement Suit*

The Federal Circuit reaffirmed its prior holdings that a successful laches defense *only* bars a patentee from recovering damages for acts of infringement occurring *before the complaint was filed*,²⁸ while equitable estoppel is a complete defense which bars the patent owner from obtaining any remedy for patent infringement (e.g., recovering damages or infringement occurring *before and after* the complaint was filed, securing an injunction against future infringement).²⁹

III. LACHES DEFENSE GENERALLY

1. *The Two Elements of a Laches Defense: Undue Delay & Material Prejudice*

The Federal Circuit reaffirmed its prior holdings that made it well settled that, to invoke the laches defense, a defendant has the burden to prove two factors:

1. the plaintiff delayed filing suit for an unreasonable and

25. *Aukerman*, 960 F.2d at 1044-45, 22 USPQ2D (BNA) at 1338 ("This court has not previously addressed the issue of what evidentiary burden must be met by litigants seeking to prove a laches or an equitable estoppel defense. Because the question of quantum in patent cases arises in every case within this area of our exclusive jurisdiction, we conclude that a uniform Federal Circuit rule should be adopted.").

26. *Aukerman*, 960 F.2d at 1045-46, 22 USPQ2D (BNA) at 1339 ("Accordingly, we hold that 'preponderance of the evidence' is the appropriate evidentiary standard to establish the facts relating to the laches issue"; and "we adopt the preponderance of evidence standard in connection with the proof of equitable estoppel factors, absent special circumstances, such as fraud or intentional misconduct.").

27. A defense is proven by a "preponderance of the evidence" when "it is more convincing to the trier than the opposing evidence." *Aukerman*, 960 F.2d at 1045, 22 USPQ2D (BNA) at 1338 (quoting MCCORMICK'S HANDBOOK OF THE LAW OF EVIDENCE § 339, at 793 (2d ed. 1972)). "The phrase 'clear and convincing evidence' means evidence producing a firm belief or conviction as to the matter sought to be established." *Trans-World Mfg. Corp. v. Al Nyman & Sons, Inc.*, 750 F.2d 1552, 1560 (Fed. Cir. 1984).

28. *Aukerman*, 960 F.2d at 1041, 22 USPQ2D (BNA) at 1335 ("[W]e will continue to hold, as a matter of policy, that laches bars relief on a patentee's claim only with respect to damages accrued prior to suit. At least on the facts presented in this case, we have no reason to revisit this accepted principle.") (citations omitted).

29. *Aukerman*, 960 F.2d at 1028, 22 USPQ2D (BNA) at 1325 ("Where an alleged infringer establishes the defense of equitable estoppel, the patentee's claim may be entirely barred.").

inexcusable length of time from the time the plaintiff knew or reasonably should have known of its claim against the defendant, and

2. the delay operated to the prejudice or injury of the defendant.³⁰

a. Unreasonable and Inexcusable Delay

As to the first factor of unreasonable and inexcusable delay, the Federal Circuit reaffirmed its prior holdings that “[t]he period of delay is measured from the time the plaintiff knew or reasonably should have known of the defendant’s alleged infringing activities to the date of suit.”³¹ However, the period does not begin prior to issuance of the patent,³² since there can be no “infringing activity” before the patent issues.³³ The Federal Circuit reiterated that “[t]he length of time which may be deemed unreasonable has no fixed boundaries but rather depends on the circumstances.”³⁴ Further, in determining whether the delay was “unreasonable and inexcusable,” the Federal Circuit explained that:

A court must also consider and weigh any justification offered by the plaintiff for its delay. Excuses which have been recognized in some instances, and we do not mean this list to be exhaustive, include: other litigation; negotiations with the accused; possibly poverty and illness under limited circumstances; wartime conditions; extent of infringement; and dispute over ownership of the patent.³⁵

Another excuse recognized by the Federal Circuit, but not mentioned in the *Aukerman* decision, is that the patentee was waiting to sue for infringement of a first patent until a second patent issued, so that a single lawsuit could be filed for infringement of both

30. *Aukerman*, 960 F.2d at 1032, 22 USPQ2D (BNA) at 1328. The Federal Circuit further stated: “Material prejudice to adverse parties resulting from the plaintiff’s delay is essential to the laches defense.” 960 F.2d at 1033, 22 USPQ2D (BNA) at 1328.

31. That is, from “the time the patentee knew, or in the exercise of reasonable diligence should have known, of the alleged infringing activity.” *Jamesbury Corp. v. Litton Indus. Prod., Inc.*, 839 F.2d 1544, 1552, 5 USPQ2D (BNA) 1779, 1785 (Fed. Cir. 1988) (emphasis added), *overruled by* *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020 (Fed. Cir. 1992).

32. *Aukerman*, 960 F.2d at 1032, 22 USPQ2D (BNA) at 1328.

33. *Gustafson, Inc. v. Intersystems Indus. Prods.*, 897 F.2d 508, 510, 13 USPQ2D (BNA) 1972, 1974 (Fed. Cir. 1990) (“It is obvious that a party cannot be held liable for ‘infringement,’ and thus not for ‘willful’ infringement, of a *nonexistent* patent, i.e., no damages are payable on products manufactured and sold before the patent issued.”) (emphasis in original).

34. *Aukerman*, 960 F.2d at 1032, 22 USPQ2D (BNA) at 1328.

35. *Aukerman*, 960 F.2d at 1033, 22 USPQ2D (BNA) at 1329 (citations omitted).

patents.³⁶

*i. Notice to the Infringer of the Reason or Excuse
for Not Suing Earlier is Not an Absolute
Prerequisite, and Application of That
Principle to the "Other Litigation"
Excuse*

Where the patentee proffers a reason or excuse for not suing the defendant earlier, the question which often arises is whether the patentee must advise the defendant of why it is not being sued. Most often this issue arises where the patentee's reason or excuse for not suing earlier is that it was engaged in "other litigation" and the patentee did not want to simultaneously maintain two separate infringement actions. Thus, the patentee was delaying its suit against the defendant until after completion of the lawsuit against the other infringer.³⁷ Under such circumstances, the Federal Circuit had expressly ruled on at least three separate occasions — in *Hottel Corporation v. Seaman Corporation*,³⁸ *Jamesbury Corporation v. Litton Industrial Products, Inc.*³⁹ and *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*⁴⁰ — that in order to excuse delay based on other litigation, the patentee *must* "give notice to the alleged infringer of [1] the existence of the other litigation and [2] of [an] intent to enforce its rights against the alleged infringer" at the conclusion of the other litigation.⁴¹ Thus, summary judgment of

36. *Meyers v. Brooks Shoe Inc.*, 912 F.2d 1459, 1452, 16 USPQ2D (BNA) 1055, 1057 (Fed. Cir. 1990) (hereinafter, "*Meyers-I*") (Federal Circuit reversed the district court's grant of summary judgment of laches in part because: "Awaiting issuance of the second patent to sue on both at once conserved both the parties' and the court's resources. It may be that there are times when a patentee must bring suit before the expected issuance of the second of two related patents, . . . but this is not one of them.") (citations omitted), *overruled by* A.C. Aukerman v. R.L. Chaides Constr. Co., 960 F.2d 1020 (Fed. Cir. 1992).

37. *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 877, 20 USPQ2D (BNA) 1045, 1050 (Fed. Cir. 1991) ("The 'other litigation' excuse normally applies when a patentee defers suit against an alleged infringer until the conclusion of another lawsuit. If the party is ultimately sued and had received proper notice, the time delay consumed by the original proceeding may be excused in evaluating whether laches occurred.").

38. 833 F.2d 1570, 4 USPQ2D (BNA) 1939 (Fed. Cir. 1987), *overruled by* A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020 (Fed. Cir. 1992).

39. 839 F.2d 1544, 5 USPQ2D (BNA) 1779 (Fed. Cir. 1988), *overruled by* A.C. Aukerman v. R.L. Chaides Constr. Co., 960 F.2d 1020 (Fed. Cir. 1992).

40. 944 F.2d 870, 20 USPQ2D (BNA) 1045 (Fed. Cir. 1991).

41. *Jamesbury*, 839 F.2d at 1553, 5 USPQ2D (BNA) at 1786. *See also* *Hottel*, 833 F.2d at 1573, 4 USPQ2D at 1940-41; and *Vaupel*, 944 F.2d at 877, 20 USPQ2D (BNA) at 1050 ("For other litigation to excuse a delay in bringing suit, there *must* be adequate notice of the proceedings to the accused infringer. The notice *must* also inform the alleged infringer of the patentee's intention of enforcing its patent upon completion of that proceeding.") (citations omitted) (emphasis added).

laches has been affirmed by the Federal Circuit where the notice met the first requirement but not the second,⁴² and where the notice met the second requirement but not the first.⁴³

42. In *Jamesbury*, plaintiff accused defendant of infringement, defendant denied infringement, and the parties met but did not resolve the matter. 839 F.2d at 1553, 5 USPQ2D (BNA) at 1786. Plaintiff then indicated in a letter to defendant that it had submitted defendant's position to its attorneys and that the subject was under consideration. 839 F.2d at 1553, 5 USPQ2D (BNA) at 1786. There was no further contact until plaintiff sued eight years later. 839 F.2d at 1553, 5 USPQ2D (BNA) at 1786. The Federal Circuit affirmed summary judgment of laches because the patentee gave notice of the existence of the other litigation (notice [1]), but not of an intent to sue the defendant after that other litigation was concluded (notice [2]). According to the Federal Circuit:

In this case, there is no question that Jamesbury notified Contromatics of the Court of Claims litigation, so it has met the first part of the test. It cannot meet the second part, however. Jamesbury never clearly indicated that it intended to enforce its rights against Contromatics after the Court of Claims litigation ended. Jamesbury failed to give adequate notice to Contromatics, as concluded by the district court.

839 F.2d at 1553, 5 USPQ2D (BNA) at 1786.

43. In *Hottel*, the "other litigation" was a pending reexamination of one of the four patents-in-suit. 833 F.2d at 1572-73, 4 USPQ2D (BNA) at 1940. Plaintiff accused defendant of infringing the four patents, defendant denied infringement, and some back-and-forth letter writing ensued. 833 F.2d at 1571-72, 4 USPQ2D (BNA) at 1939-40. During that time plaintiff (through the inventor) filed for reexamination of one of the four patents. 833 F.2d at 1571-72, 4 USPQ2D (BNA) at 1939-40. The reexamination was granted and the patent office examiner issued a final, appealable rejection of all the claims of the patent. 833 F.2d at 1571-72, 4 USPQ2D (BNA) at 1939-40. Plaintiff (through the inventor) appealed that decision in the patent office to the Board of Patent Appeals. 833 F.2d at 1571-72, 4 USPQ2D (BNA) at 1939-40.

While that appeal was pending, and before the Board reversed the examiner's rejections, plaintiff sent defendant a letter "Re: Huddle Patents" stating, "Please be advised that we are appealing a decision rendered in the above matter and intend to pursue actively our patent claims upon receipt of the ruling." 833 F.2d at 1572, 4 USPQ2D (BNA) at 1940. The notice letter was found to be deficient because, while the letter met the second notice requirement (an intent to sue after "other litigation" concludes), the letter did not meet the first requirement (adequate notice of the "other litigation"). More specifically, "the letter shows that it did not specify the patent or patents involved and did not indicate the nature of the proceedings or the decision appealed" and, therefore, "did not provide adequate notice of a proceeding relied on to excuse the delay." 833 F.2d at 1573, 4 USPQ2D (BNA) at 1941.

Note should be made that the Federal Circuit stated that "[b]ecause the notice was deficient we need not decide whether a reexamination proceeding may qualify as 'other litigation' or whether a proceeding with respect to one patent may provide an excuse for not bringing suit for infringement of other related patents." 833 F.2d at 1573 n.2, 4 USPQ2D (BNA) at 1941 n.2. Both questions were answered in subsequent cases. See *Vaupel*, 944 F.2d at 877, 20 USPQ2D (BNA) at 1050 (awaiting patent to emerge from a reissue proceeding may be a valid excuse with the reissue proceeding qualifying as "other litigation"; reexamination and reissue proceedings should both be treated the same since they both are patent office proceedings where the validity of the claims of an issued patent are determined); and *Meyers v. Brooks Shoe Inc.*, 912 F.2d 1459, 1462, 16 USPQ2D (BNA) 1055, 1057 (Fed. Cir. 1990) (*Meyers-I*) (awaiting issuance of second patent may be a valid excuse for not suing on a first patent). See also *Collins Licensing L.P. v. Am. Tel. And Tel. Co.*, 1992 U.S. Dist. LEXIS 4648, at *2 (W.D. Tex. Mar. 23, 1992) (citing *Vaupel* for conclusion that "[t]he 1989 reexamination is analogous to a reissue proceeding, and thus it constitutes 'other litigation' sufficient to toll the

Notice is important for several reasons. It informs the accused infringer of the existence of the suit and that a subsequent suit will be filed against him. He can then change his activities to avoid liability. He can also bring a declaratory judgment action if the delay in waiting for a judicial determination would be a burden upon his proposed activities.⁴⁴

In *Vaupel*, the Federal Circuit explained that the notice of the "other litigation" need not come from the patentee; notice "in fact" from other sources is adequate.⁴⁵ Further, the notice of an intent to enforce its rights against the infringer at the conclusion of the other litigation need not be "expressly stated"; it can be understood from the accumulation of correspondence and communications between the patentee and the infringer.⁴⁶ In other words, "[w]hat is important is whether [the infringer] MEI had reason to believe [that] it was likely to be sued."⁴⁷ That was the case in *Vaupel* where the infringer actively participated in the "other litigation" because of concern and an expectation that it would be sued when the other litigation terminated.⁴⁸

In *Aukerman*, the Federal Circuit changed all this. In opposition to Chaides' motion for summary judgment, Aukerman sought to excuse its delay by "present[ing] evidence that, during part of the delay, it was engaged in other litigation," but "[t]he district court rejected this excuse because at no time did Aukerman give Chaides notice of such litigation and of its intention to sue Chaides upon its conclusion."⁴⁹ The Federal Circuit held that this was error. According to the *Aukerman* court, "[t]he equities may or may not require that the plaintiff communicate its reasons for delay to the

laches clock"); *Hemstreet v. Computer Entry Sys. Corp.*, 972 F.2d 1290, 23 USPQ2D 1860 (BNA) (Fed. Cir. 1992) (hereinafter, "*Hemstreet-I*") (post-*Aukerman* case in which the Federal Circuit reversed the district court's grant of summary judgment of laches in part because of the plaintiff's "other litigation" excuse; the "other litigations" were a patent infringement suit with a third party and a reexamination of the subject patent instituted by that third party).

44. *Vaupel*, 944 F.2d at 877, 20 USPQ2D (BNA) at 1050.

45. *Vaupel*, 944 F.2d at 877, 20 USPQ2D (BNA) at 1050 ("To establish whether such notice was given, the district court must look not only at the actions of the patentee, but also at evidence showing whether the alleged infringer was *in fact* on notice of an existing lawsuit.") (emphasis in original).

46. See *Vaupel*, 944 F.2d at 878, 20 USPQ2D (BNA) at 1051.

47. *Vaupel*, 944 F.2d at 878, 20 USPQ2D (BNA) at 1051.

48. In *Vaupel*, the other litigation was a reissue proceeding in which the infringer actively participated as a protester. The Federal Circuit held that a reissue proceeding over the subject patent may be the "other litigation." 944 F.2d at 877, 20 USPQ2D (BNA) at 1050. According to the Federal Circuit, "a reissue proceeding . . . should be treated similarly to infringement litigation for purposes of laches." 944 F.2d at 877, 20 USPQ2D (BNA) at 1050.

49. *Aukerman*, 960 F.2d at 1039, 22 USPQ2D (BNA) at 1334.

defendant.”⁵⁰ More specifically:

... there can be no rigid requirement in judging a laches defense that such notice *must* be given. If a defendant is, for example, aware of the litigation from other sources, it would place form over substance to require a specific notice. Where there is prior contact, the overall equities may require appropriate notice, as in *Jamesbury*. However, a notice requirement is not to be rigidly imposed as the district court did in this case.⁵¹

The Federal Circuit thus went from an absolute rule requiring that “in order to excuse delay based on other litigation, the patentee *must* give notice to the alleged infringer”⁵² to a more vague principle requiring only that the totality of the circumstances be examined to determine whether the “overall equities . . . require appropriate notice.”⁵³

What is particularly troublesome is that the Federal Circuit never indicated that it was overruling its prior precedent, when that is unmistakably what it was in fact doing. In *Aukerman*, there was no notice whatsoever to the alleged infringer that suit was not being brought in 1979 because of “other litigation” or for any other reason. Indeed, after Chaides responded that it was not going to take a license and if Aukerman did not like that it could sue, “[t]here was no further correspondence or contact between the parties for more than eight years.”⁵⁴ Under *Hottel*, *Jamesbury* and *Vaupel*, that *alone* would have defeated the “other litigation” defense proffered by Aukerman. And the district court, relying on that precedent, correctly so held. Here, the Federal Circuit *sub silentio* overruled that precedent and, on that basis, reversed the district court’s decision. The end result being that, whereas before it was relatively easy to defeat an “other litigation” excuse on summary judgment — just establish that without dispute of material fact adequate notice of the other litigation was not given — it is now much more difficult, if not virtually impossible, to challenge an “other litigation” excuse on summary judgment. The “overall equities,” when viewed in the light most favorable to the patentee, as must be done on summary judgment, will invariably give rise to a reasonable inference that notice was not required so that summary judgment of laches is improper.⁵⁵

50. *Aukerman*, 960 F.2d at 1033, 22 USPQ2D (BNA) at 1329.

51. *Aukerman*, 960 F.2d at 1039, 22 USPQ2D (BNA) at 1334 (citations omitted).

52. *See supra*, note 41 and accompanying text.

53. *Aukerman*, 960 F.2d at 1039, 22 USPQ2D (BNA) at 1334.

54. *Aukerman*, 960 F.2d at 1027, 22 USPQ2D (BNA) at 1323.

55. Summary judgment cannot be granted unless the movant establishes that there is no

ii. The "De Minimis Infringement" Excuse

A second excuse sometimes proffered by a patentee to explain delay in bringing suit is that the infringement was *de minimis* such that suit against the alleged infringer was not financially worthwhile initially. Prior to *Aukerman*, the Federal Circuit had not addressed this excuse in any reported decision. In pre-Federal Circuit cases, however, the courts generally required that the patentee give notice to the alleged infringer that the patentee will enforce the patent when it becomes financially worthwhile.⁵⁶ Thus, a notice requirement was in place for the *de minimis* excuse, much the same as it had been for the other litigation excuse.

However, in *Aukerman*, the Federal Circuit ruled that the district court had erred in rejecting the patentee's *de minimis* infringement excuse, even though there was apparently no notice from the patentee that it would enforce the patent when it became financially

genuine issue of material fact and that the movant is entitled to a judgment as a matter of law based on the uncontroverted facts. *Armco, Inc. v. Cyclops Corp.*, 791 F.2d 147, 149 (Fed. Cir. 1986). All evidence must be viewed in the light most favorable to the non-movant (opposing party), all reasonable inferences must be drawn in the non-movant's favor, and all doubt over factual issues must be resolved in the non-movant's favor. *Id.*

A case which illustrates the significance of the change in the law announced in *Aukerman* is *Hemstreet v. Computer Entry Sys. Corp.*, 972 F.2d 1290, 23 USPQ2D (BNA) 1860 (Fed. Cir. 1992) (*Hemstreet-I*). In *Hemstreet-I*, a post-*Aukerman* case, the Federal Circuit reversed the district court's grant of summary judgment of laches and equitable estoppel. As to laches, the Federal Circuit found that, on the record before the district court, the "other litigation" excuse showed the delay to be both reasonable and excusable despite plaintiff's failure to explicitly advise defendant that it would be sued at the conclusion of the "other litigation" between plaintiff and Burroughs. 972 F.2d at 1293, 23 USPQ2D at 1863. The Federal Circuit explained:

It is true that prior precedent could be read to require explicit notice to the defendant of both the existence of the other proceedings and the patentee's intent to enforce its rights against the alleged infringer at the conclusion of other litigation. *Aukerman* has clarified that this is far from a hard and fast requirement. Instead, *Aukerman* restores equitable flexibility: 'The equities may or may not require that the plaintiff communicate its reasons for delay to the defendant.'

Here, we note that during the 1976-1989 period Hemstreet was busy enforcing his patent rights elsewhere, and indeed for a period of the delay [more specifically, for about three of the approximately six years of delay] had no valid patent rights to enforce, as the *Burroughs* trial court had erroneously held the patent unenforceable [in the other litigation]. On the facts of record before us, the delay involved here could not be considered unreasonable and inexcusable.

972 F.2d at 1293, 23 USPQ2D at 1863.

56. See, e.g., *Dymo Indus., Inc. v. Monarch Marking Sys., Inc.*, 474 F.Supp. 412, 415, 206 USPQ (BNA) 185, 189 (N.D. Tex. 1979) ("At the minimum, [the patentee] should have notified [the infringer] that it intended to enforce the patent whenever [the infringer's] position in the market rendered such a suit feasible.").

worthwhile.⁵⁷ Apparently, the Federal Circuit believed that given the totality of the circumstances, an inference could be drawn that the overall equities did not require notice because the defendant knew or should have known that the patentee was not suing because of the *de minimis* nature of the infringement, but that the patentee would sue if the infringement became more substantial. After all, the defendant responded to the charge of infringement by stating that any responsibility was Gomaco's, and that if Aukerman wished to sue Chaides "for \$200-\$300 a year," Aukerman should do so.⁵⁸ In other words, the defendant was telling the patentee not to sue because it was not manufacturing the accused product, and its use of the accused product was insubstantial. But both of these facts changed and that is what led the patentee to sue the defendant.⁵⁹

In reaching its decision, the Federal Circuit indicated that if *de minimis* infringement is an adequate excuse for a delay until the infringement becomes substantial, the delay (if any) after the patentee knew or should have known that the infringement had become or was becoming substantial must be separately considered. The *de minimis* infringement may only excuse part of the delay period. In this case, however, on summary judgment "[i]t could not be inferred against the patentee that these changed circumstances [the conversion from insubstantial infringement to substantial infringement] should have been known to the patentee or were immaterial to the determination of laches."⁶⁰ The issue of when the patentee

57. The Federal Circuit did not expressly mention the notice requirement issue with respect to the *de minimis* infringement excuse. However, the Federal Circuit did say earlier, with reference to excuses *in general*, that "[t]he equities may or may not require that the plaintiff communicate its reasons for delay to the defendant." *Aukerman*, 960 F.2d at 1033, 22 USPQ2D (BNA) at 1329. Moreover, the Federal Circuit did overturn the district court's rejection of the excuse even though there was no notice. 960 F.2d at 1039, 22 USPQ2D (BNA) at 1334. And the comments that the Federal Circuit made with respect to the lack of an absolute notice requirement relative to the other litigation excuse seem equally applicable to all other excuses, including the *de minimis* infringement excuse.

58. *Aukerman*, 960 F.2d at 1026-27, 22 USPQ2D (BNA) at 1323.

59. The following comment was made by the Federal Circuit with respect to the equitable estoppel defense, but may be equally applicable to the laches defense:

While the above factors favor the nonenforcement inference, Chaides' further statement that Aukerman would only recover \$200-\$300 a year could lead one in Chaides' position to infer that Aukerman did not sue because the amount in issue was *de minimis*, not that Aukerman was abandoning its claim against Chaides for all time regardless of quantum. At most Aukerman could merely have been waiving an infringement claim for \$300.00 per year.

In view of the different inferences which could be drawn from the exchange of correspondence, it is clear that the court drew an unfavorable inference against Aukerman. That is impermissible on summary judgment.

960 F.2d at 1044, 22 USPQ2D (BNA) at 1337-38.

60. *Aukerman*, 960 F.2d at 1039, 22 USPQ2D (BNA) at 1334.

knew or should have known that the infringement had become substantial and, therefore, whether the delay thereafter was excused, had to be tried. It was inappropriate for summary judgment.⁶¹

b. Material Prejudice

As to the second factor — material prejudice to the defendant occasioned by the plaintiff's delay in filing suit — the Federal Circuit explained that "[s]uch prejudice may be either economic or evidentiary."⁶² "Evidentiary, or 'defense' prejudice, may arise by reason of a defendant's inability to present a full and fair defense on the merits due to the loss of records, the death of a witness, or the unreliability of memories of long past events, thereby undermining the court's ability to judge the facts."⁶³ This type of prejudice must be proven with particularity; broad, general, conclusory allegations will not suffice.⁶⁴

The Federal Circuit explained in *Aukerman* that "[e]conomic prejudice may arise where a defendant and possibly others will suffer the loss of monetary investments or incur damages which likely would have been prevented by earlier suit."⁶⁵ That is not a new

61. According to the Federal Circuit:

Similarly, we believe the court erred in resolving the issue of whether the defendant's infringing activities changed sufficiently to disrupt the laches period. It is not disputed that defendant's conduct changed during the laches time frame both by its manufacturing its own slip-forming device and by greatly increasing the amount of asymmetrical wall it poured. It could not be inferred against the patentee that these changed circumstances should have been known to the patentee or were immaterial to the determination of laches. Upon the record before us, summary judgment of laches was improperly granted. The issue of laches must be tried.

960 F.2d at 1039, 22 USPQ2D (BNA) at 1334.

62. *Aukerman*, 960 F.2d at 1033, 22 USPQ2D (BNA) at 1328.

63. *Aukerman*, 960 F.2d at 1033, 22 USPQ2D (BNA) at 1328. See also 5 CHISUM, PATENTS § 19.05[2][c] at 19-443 (1992 ed.) ("The courts universally accept this [type of prejudice] as sufficient prejudice for purposes of laches," referring to "events that impair the defendant's ability to defend a patent suit[, i]nclud[ing] . . . the death of critical witnesses, the dimming of memories, and the loss of documents.").

64. In *Meyers v. Asics Corp.*, 974 F.2d 1304, 24 USPQ2D (BNA) 1036 (Fed. Cir. 1992) (hereinafter, "*Meyers-II*"), a post-*Aukerman* case, the Federal Circuit reversed the district court's grant of summary judgment of laches and equitable estoppel. As to laches, the Federal Circuit rejected the defendants' claim of "evidentiary prejudice" because:

Defendants also argue that they suffered evidentiary prejudice — loss of key witnesses and loss of documentary evidence. However, none of the defendants state exactly what particular prejudice it suffered from the absence of these witnesses or evidence. Conclusory statements that there are missing witnesses, that witnesses' memories have lessened, and that there is missing documentary evidence, are not sufficient.

974 F.2d at 1308, 24 USPQ2D at 1039.

65. *Aukerman*, 960 F.2d at 1033, 22 USPQ2D (BNA) at 1329.

concept. It has been settled law for decades that where the infringer expands or invests in its infringing business during the period of plaintiff's delay in filing suit (e.g., builds new factories, hires more employees, secures substantial financing, increases sales of infringing products, introduces new infringing products), that constitutes "economic prejudice" sufficient to establish that element of a laches defense.⁶⁶

Of course, where the defendant merely continues selling infringing product at a constant rate using the same facilities and personnel during the period of plaintiff's delay in filing suit, she suffers prejudice in the sense that infringement liability is incurred during that period. However, the Federal Circuit in *Aukerman* was careful to note that such damages, which are "merely . . . attributable to a finding of liability for infringement" and which, therefore, "arise in every suit," do not *alone* constitute the type of economic prejudice adequate for a laches defense.⁶⁷ There *typically* would have to be some "*change* in the economic position of the alleged infringer during the period of delay,"⁶⁸ such as substantial expansion of the infringing business during the period of delay. Later Federal Circuit decisions make plain that the defendant *must* establish that the change in economic position resulted from the delay; *i.e.*, the

66. *Sun Studs Inc. v. ATA Equip. Leasing, Inc.*, 872 F.2d 978, 993, 10 USPQ2D (BNA) 1338, 1350-51 (Fed. Cir. 1989) (while the Federal Circuit reversed a jury verdict of laches, the Federal Circuit also found no error in a jury instruction that: "Prejudice arises where on account of delay, the alleged infringer made a substantial investment in building up its business. . . ."); *A.C. Aukerman Co. v. Miller Formless Co. Inc.*, 693 F.2d 697, 701 (7th Cir. 1982) (in finding laches the court explained that "[a]s to the problem of prejudice to the defendant through the long delay, there is no substantial question. [The infringer's] business continued and expanded while the plaintiff was postponing suit."); *Lemelson v. Carolina Enter's, Inc.*, 541 F.Supp. 645, 657, 216 USPQ (BNA) 249, 258 (S.D.N.Y. 1982) (the "change" in position which led the court to find material prejudice included continuous marketing of infringing toys, entering into a license with another company to market a new toy containing the infringing device, development of a new toy equipped with the infringing device); *Coleman v. Corning Glass Works*, 619 F.Supp. 950, 955, 226 USPQ (BNA) 991, 993 (W.D.N.Y. 1985) (in finding laches the court explained that "it is settled [law] that the successful expansion of an infringer's business is itself the kind of prejudice which will support the defense of laches"), *aff'd*, 818 F.2d 874 (Fed. Cir. 1987); *Jackson Jordan, Inc. v. Plasser Am. Corp.*, 219 USPQ (BNA) 922, 926 (E.D. Va. 1983) (in finding laches the court explained that one form of prejudice was the investment in a new plant to make the infringing product); and *Olympia Werke Aktiengesellschaft v. General Elec. Co.*, 545 F.Supp. 598, 609-10, 215 USPQ (BNA) 720, 729 (W.D. Va. 1982) (in finding laches the court explained that some forms of prejudice were the investment of large sums of money in the development and promotion of the accused device, and in plant facilities and in inventory and machinery for production of the device; increase in sales many times over; the development and introduction of other models of accused devices and accessories and options therefor), *aff'd* 712 F.2d 74 (4th Cir. 1983).

67. *Aukerman*, 960 F.2d at 1033, 22 USPQ2D (BNA) at 1329.

68. *Aukerman*, 960 F.2d at 1033, 22 USPQ2D (BNA) at 1329 (emphasis in original).

change would not have occurred had the plaintiff sued earlier.⁶⁹ Another *change* in circumstances constituting economic prejudice might be the discontinuance of a general reserve account to pay infringement damages to plaintiff in the event a suit is brought.⁷⁰

However, the Federal Circuit in *Aukerman* was also careful to

69. For example, in *Meyers v. Asics Corp.*, 974 F.2d 1304, 24 USPQ2D (BNA) 1036 (Fed. Cir. 1992) (*Meyers-II*), the Federal Circuit reversed the district court's grant of summary judgment of laches and equitable estoppel. As to laches, the Federal Circuit rejected the defendants' claim of "economic prejudice" because there was no showing that the defendants would have done anything differently had they been sued earlier. 974 F.2d at 1307-8, 24 USPQ2D (BNA) at 1038-39. More specifically, the Federal Circuit stated:

[Defendants] Asics, ATC and Hyde all assert that since [plaintiff] Meyers' initial contacts with them, they have spent substantial amounts of money to design, develop and promote many new and different shoe models that Meyers now alleges infringe his patents. There is no dispute that defendants have suffered an economic detriment, the question is whether this prejudice *resulted from* Meyers' delay.

None of the defendants submitted evidence that they curtailed design and development of shoes in response to Meyers' suit once it was actually filed. Moreover, the sales data submitted by the defendants to support their assertion of prejudice are not conclusive. Sales of the various models were somewhat erratic, and do not show any clear trend. Finally, the evidence shows that none of the defendants were concerned that its products might infringe Meyers' patents, and does not show that any of the defendants would have acted differently had Meyers sued earlier.

974 F.2d at 1308, 24 USPQ2D (BNA) at 1038-39. Another illustrative post-*Aukerman* case is *Hemstreet v. Computer Entry Sys. Corp.*, 972 F.2d 1290, 23 USPQ2D (BNA) 1860 (Fed. Cir. 1992) (hereinafter, *Hemstreet-I*), in which the Federal Circuit reversed the district court's grant of summary judgment of laches and equitable estoppel. As to laches, the Federal Circuit made the following comments regarding the defendant's claim of "economic prejudice":

[T]he record reflects that [defendant] CES had expenditures of over \$23 million on research and development, \$6.5 million on direct marketing costs, and \$20 million to expand or consolidate manufacturing facilities. But these expenditures have no explicitly proven nexus to the patentee's delay in filing suit, as *Aukerman* requires for a finding of prejudice. It is not enough that the alleged infringer changed his position — i.e., invested in production of the allegedly infringing device. The change must be because of and as a result of the delay, not simply a business decision to capitalize on a market opportunity. See *Aukerman*, 960 F.2d at 1033, 22 USPQ2D at 1329. Further, we note that CES' prejudice argument is severely undercut by [plaintiff] Hemstreet's provision of explicit notice of the *Burroughs* litigation and implicit suggestion that CES would soon face litigation if it refused to license. Presumably, CES itself read the letter in that light, since it promptly inquired about licensing arrangements. These factors should be carefully examined by the trial court if the defendant chooses on remand to pursue a laches defense.

972 F.2d at 1293-94, 23 USPQ2D (BNA) at 1863 (citations omitted).

70. See e.g., *Olympia Werke Aktiengesellschaft v. General Electric Co.*, 545 F.Supp. 598, 610, 215 USPQ (BNA) 720, 729 (W.D. Va. 1982) (in finding laches court explained that one form of prejudice was the creation and then termination of a general reserve account based upon 5% sales assessment for any potential patent litigation), *aff'd*, 712 F.2d 74 (4th Cir. 1983).

explain that such a change in circumstances is not always essential to a finding of economic prejudice. The court explained that a patentee may not "intentionally lie silently in wait watching damages escalate, particularly where an infringer, if he had notice, could have switched to a noninfringing product."⁷¹ That too is not a new principle. It has long been the law that if the defendant could have turned to a noninfringing alternative, or initiated development of such a product, the lost opportunity to do so, and thus mitigate her potential damages, constitutes economic prejudice adequate to support a laches defense.⁷²

Thus, according to the *Aukerman* court, "economic prejudice is not a simple concept but rather is likely to be a slippery issue to resolve."⁷³

2. The Presumption of Laches

35 U.S.C. § 286 provides that "no recovery shall be had for any [patent] infringement committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action."⁷⁴ From that the Federal Circuit decided in 1984 that a delay of more than six years in filing suit would give rise to a presumption of laches; that is, unreasonable/inexcusable delay by the patentee and prejudice to the infringer arising therefrom would both be presumed when the delay in bringing suit was more than six years.⁷⁵ In *Aukerman*, the Federal Circuit reaffirmed that decision, explaining "that the presumption of laches based on the relevant six-year period, previously adopted in our precedent, should be maintained."⁷⁶ Thus, "[p]rima facie, the underlying critical factors

71. *Aukerman*, 960 F.2d at 1033, 22 USPQ2D (BNA) at 1329 (citation omitted).

72. *Sun Studs Inc. v. ATA Equip. Leasing, Inc.*, 872 F.2d 978, 993, 10 USPQ2D (BNA) 1338, 1350-51 (Fed. Cir. 1989) (while the Federal Circuit reversed a jury verdict of laches, the Federal Circuit also found no error in a jury instruction that: "'Prejudice arises where on account of delay, . . . the accused infringer would have avoided the alleged infringing conduct by modifying its business.'"); *In re Yarn Processing Patent Validity Litig.*, 602 F.Supp. 159, 172, 225 USPQ (BNA) 765, 774 (W.D.N.C. 1984) (in finding laches court explained that one form of prejudice was the "lost opportunities to mitigate damages"); and *Potter Instrument Co. Inc. v. Storage Technology Corp.*, 207 USPQ 763, 769 (E.D. Va. 1980) (in finding laches court explained that one form of prejudice was that the defendants "could and would have circumvented [the patentee's] patent claims, had they been timely sued for infringement") *aff'd*, 642 F.2d 190 (4th Cir. 1981), *cert. denied*, 454 U.S. 832 (1981).

73. *Aukerman*, 960 F.2d at 1033, 22 USPQ2D (BNA) at 1329.

74. 35 U.S.C. § 286 (1988).

75. *Leinoff v. Louis Milona & Sons, Inc.*, 726 F.2d 734, 741-42, 220 USPQ (BNA) 845, 850 (Fed. Cir. 1984), *overruled by* *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020 (Fed. Cir. 1992).

76. *Aukerman*, 960 F.2d at 1035, 22 USPQ2D (BNA) at 1331.

of laches are presumed upon proof that the patentee delayed filing suit for more than six years after actual or constructive knowledge of the defendant's alleged infringing activity."⁷⁷ "Without the presumption, the two facts of unreasonable delay and prejudice might reasonably be inferred from the length of the delay, but not necessarily. With the presumption, these facts *must* be inferred, absent rebuttal evidence."⁷⁸

3. *The Laches Presumption Shifts the "Burden of Coming Forward" With Evidence but the "Ultimate Burden of Proof" Remains With the Accused Infringer*

As noted above, the defendant (infringer) has the burden of proving his laches defense by a preponderance of the evidence. However, what happens when the defendant establishes a presumption of laches? In *Aukerman*, the Federal Circuit acknowledged that "[n]umerous decisions," including at least one by a panel of the Federal Circuit, "indicate or suggest that the defendant's establishing a six-year delay shifts the burden of proof, that is, the ultimate burden of persuasion, from the defendant to the patentee."⁷⁹ In other words, once the presumption is established, the burden shifts to the plaintiff (patent owner) to prove by a preponderance of the evidence that the delay was reasonable or excusable, or that the defendant sustained no damage as a result of the delay. Empirical data demonstrates that rarely, if ever, has a plaintiff been able to meet that burden. But in *Aukerman*, the Federal Circuit changed all this.

In *Aukerman*, the Federal Circuit concluded that "[t]his view of the laches presumption is legally unsound."⁸⁰ So the Federal Circuit overruled those prior decisions and pronounced, for the very first time, that the laches presumption is of the type described

77. *Aukerman*, 960 F.2d 1035, 22 USPQ2D (BNA) at 1331.

78. *Aukerman*, 960 F.2d at 1037, 22 USPQ2D (BNA) at 1332 (emphasis in original).

79. *Aukerman*, 960 F.2d at 1307, 22 USPQ2D (BNA) at 1332 ("Numerous decisions indicate or suggest that the defendant's establishing a six-year delay shifts the burden of proof, that is, the ultimate burden of persuasion, from the defendant to the patentee. For example, the *Leinoff* [Federal Circuit] decision could be read to take that position. 726 F.2d at 742.").

Leinoff does much more than "indicate or suggest" this; *Leinoff* expressly states it. In *Leinoff*, the court stated that: The presumption "shifts the burden . . . to the patent owner now to prove the existence and reasonableness of such an excuse" and "[t]he patent owner . . . bears the additional burden of showing lack of injury to the infringer caused by the delay"; "the burden of showing inexcusable and unreasonable delay and material prejudice is no longer upon [infringer] Milona." 726 F.2d at 742, 220 USPQ (BNA) at 850.

80. *Aukerman*, 960 F.2d at 1037, 22 USPQ2D (BNA) at 1332.

in Rule 301 of the *Federal Rules of Evidence*, to wit, a “bursting bubble” “presumption [which] has the effect of shifting the burden of going forward with evidence, not the burden of persuasion.”⁸¹ More specifically, the Federal Circuit explained:

As finally adopted after much scholarly debate, Rule 301 embodies what is known as the ‘bursting bubble’ theory of presumptions. Under this theory, a presumption is not merely rebuttable but completely vanishes upon the introduction of evidence sufficient to support a finding of the nonexistence of the presumed fact. In other words, the evidence must be sufficient to put the existence of a presumed fact into genuine dispute. The presumption compels the production of this minimum quantum of evidence from the party against whom it operates, nothing more. In sum, a presumption is not evidence. If the patentee presents a sufficiency of evidence which, if believed, would preclude a directed finding in favor of the infringer, the presumption evaporates and the accused infringer is left to its proof. That is, the accused infringer would then have to satisfy its burden of persuasion with actual evidence.⁸²

Elimination of the presumption does not mean the patentee precludes the possibility of a laches defense; it does mean, however, that the presumption of laches plays no role in the ultimate decision. The facts of unreasonable delay and prejudice then must be proved and judged on the totality of the evidence presented.⁸³

Finally, we reiterate that, at all times, the defendant bears the ultimate burden of persuasion of the affirmative defense of laches. To the extent statements in [prior Federal Circuit Court decisions], or other precedent may suggest otherwise, they are expressly overruled. The burden of persuasion does not shift by reason of the patentee’s six-year delay.⁸⁴

81. *Aukerman*, 960 F.2d at 1028, 22 USPQ2D (BNA) at 1325.

82. *Aukerman*, 960 F.2d at 1037-38, 22 USPQ2D (BNA) at 1332 (citations omitted). Rule 301 of the Federal Rules of Evidence, entitled “Rule 301. Presumptions in General Civil Actions and Proceedings,” provides that

[i]n all civil actions and proceedings not otherwise provided for by Act of Congress or by these rules, a presumption imposes on the party against whom it is directed the burden of going forward with evidence to rebut or meet the presumption, but does not shift to such party the burden of proof in the sense of the risk of nonpersuasion, which remains throughout the trial upon the party on whom it was originally cast.

FED. R. EVID. 301.

83. *Aukerman*, 960 F.2d at 1038, 22 USPQ2D (BNA) at 1333.

84. *Aukerman*, 960 F.2d at 1038, 22 USPQ2D (BNA) at 1333 (citations omitted).

4. *Bursting the Bubble: Rebutting the Laches Presumption*

The Federal Circuit explained how the patentee may rebut the laches presumption and burst the bubble:⁸⁵

Once a presumption of laches arises, the patentee may offer proof directed to rebutting the laches factors. Such evidence may be directed to showing either that the patentee's delay was reasonable or that the defendant suffered no prejudice or both. By raising a genuine issue respecting either factual element of a laches defense, the presumption of laches is overcome.

Thus, the presumption of laches may be eliminated by offering evidence to show an excuse for the delay or that the delay was reasonable, even if such evidence may ultimately be rejected as not persuasive. Such evidence need only be sufficient to raise a genuine issue respecting the reasonableness of the delay to overcome the presumption. Evidence, for example, directed to the excuses discussed in section III B, *supra*, will eliminate the laches presumption if sufficient to raise a genuine issue.

...

A patentee may similarly eliminate the presumption with an offer of evidence sufficient to place the matters of defense prejudice and economic prejudice genuinely in issue. Thus, the patentee may eliminate the presumption by offering proof that no *additional* prejudice occurred in the six-year time period, *i.e.*, that evidence respecting an alleged infringer's defenses remains available substantially as before the delay and that economic prejudice of the type delineated in section III B, *supra*, has not occurred.⁸⁶

5. *Summary of the Laches Presumption after Aukerman and its Impact on Future Cases*

In summary, the defendant has the initial burden of proving by a preponderance of the evidence that the plaintiff's delay in filing suit was unreasonable and inexcusable, and that the defendant sustained damage from (*i.e.*, was materially prejudiced by) the delay.

85. That is, of course, in addition to showing that the presumption does not in fact exist:

As an initial response to the defendant's evidence of at least a six-year delay, a patentee may offer proof that the delay has not in fact been six years that is, that the time it first learned or should have known of the infringement after the patent issued was within six years. If a patentee is successful on this factual issue, no presumption arises.

Aukerman, 960 F.2d at 1038, 22 USPQ2D (BNA) at 1332-33 (citation omitted).

86. *Aukerman*, 960 F.2d at 1038, 22 USPQ2D (BNA) at 1333 (emphasis in original) (citations omitted).

But if the defendant can proffer evidence that the plaintiff delayed more than six years in filing suit, then laches is presumed. The defendant will prevail on his laches defense *unless* the plaintiff offers evidence of a legitimate reason or excuse for the delay, or evidence indicating that the defendant in fact suffered no damage from the delay. It is much more likely that the plaintiff will submit credible evidence of the former (a reason or excuse for the delay), than the latter (no damage to the defendant).⁸⁷ In any event, once the plaintiff comes forward with that rebuttal evidence, everything reverts back to the beginning. The defendant will not succeed unless he proves, by a preponderance of the evidence, that the plaintiff's delay in filing suit was *unreasonable* and *inexcusable*, and that the defendant sustained damage from the delay. The plaintiff does not have to prove the opposite. Only if the trier of fact, judge or jury, concludes that it is more likely than not that the plaintiff's delay was unreasonable and inexcusable, and that there was prejudice to the defendant therefrom, will the defendant prevail on his laches defense. If the trier instead decides that the opposite is more likely, the defendant loses. If the trier cannot make up his mind, and cannot decide which is more likely (*e.g.*, it is equally likely that the delay was reasonable or unreasonable under the circumstances), the defendant still loses. A tie goes to the plaintiff. Under pre-*Aukerman* precedent, the tie would have gone to the defendant, since under that precedent the presumption shifted the *burden of proof* to the plaintiff to disprove the elements of laches (*i.e.*, prove the *nonexistence* of those elements). But, under *Aukerman*, that is no longer the case. The *burden of proof* remains at all times with the defendant; the defendant must prove the existence of both laches elements.

The change in the law occasioned by *Aukerman* is quite dramatic. Before *Aukerman*, summary judgment of laches was relatively commonplace where the delay in filing suit was more than six years.⁸⁸ The patentee could not easily prove the non-existence of the two laches factors once the presumption shifted the burden of

87. It will be the rare case indeed that after a six year delay the plaintiff can produce evidence that there was no "evidentiary or defense prejudice" in the form of fading memories or lost documents, or "economic prejudice" in the form of an expanded infringing business.

88. See, *e.g.*, *Hottel Corp. v. Seaman Corp.*, 833 F.2d 1570, 1573, 4 USPQ2D (BNA) 1939, 1941 (Fed. Cir. 1987) (summary judgment of laches affirmed), *overruled by* A.C. Aukerman v. R.L. Chaides Constr. Co., 960 F.2d 1020 (Fed. Cir. 1992); and *Jamesbury Corp. v. Litton Indus. Prod., Inc.*, 839 F.2d 1544, 1553, 5 U.S.P.O.2d 1779, 1786 (Fed. Cir. 1988) (same), *overruled by* A.C. Aukerman v. R.L. Chaides Constr. Co., 960 F.2d 1020 (Fed. Cir. 1992).

proving such non-existence to the patentee. Now, according to the companion opinion of Judge Plager in *Aukerman*, "[n]o lawyer . . . should have any difficulty in creating the factual showing that will cause both parts of the presumption to 'burst'."⁸⁹ Post-*Aukerman* cases prove the correctness of Judge Plager's comments.⁹⁰

IV. EQUITABLE ESTOPPEL DEFENSE GENERALLY

1. *The Three Elements of an Estoppel Defense*

The Federal Circuit set out three elements which "must be established to bar a patentee's suit by reason of equitable estoppel."⁹¹ Each element is discussed separately below.

a. Misleading Conduct by the Patentee

The first element of an equitable estoppel defense is the presence of misleading conduct by the patentee. That is, "[t]he patentee, through misleading conduct, leads the alleged infringer to reasonably infer that the patentee does not intend to enforce its patent against the alleged infringer."⁹² The Federal Circuit explained

89. *Aukerman*, 960 F.2d at 1047, 22 USPQ2D (BNA) at 1340 (Judge Plager concurring in part and dissenting in part; Judge Plager dissented only to the extent that he would abolish the presumption altogether).

90. On February 11, 1993, the author conducted a computerized search of the LEXIS database for post-*Aukerman* patent infringement decisions which explicitly cited *Aukerman* with respect to the doctrines of laches and estoppel. The cases uncovered in this search were: *Meyers v. Asics Corp.*, 974 F.2d 1304, 24 USPQ2D (BNA) 1036 (Fed. Cir. 1992) (*Meyers-II*) (Federal Circuit reversed district court's grant of summary judgment of laches and equitable estoppel); *Hemstreet v. Computer Entry Sys. Corp.*, 972 F.2d 1290, 23 USPQ2D (BNA) 1860 (Fed. Cir. 1992) (*Hemstreet-I*) (same); *Hemstreet v. Lundy Elec. & Sys., Inc.*, 1992 U.S. App. LEXIS 19153 (Fed. Cir. Aug. 14, 1992) (same; unpublished); *Hemstreet v. Bantec, Inc.*, 1992 U.S. App. LEXIS 19150 (Fed. Cir. Aug. 14, 1992) (same; unpublished); *Emhart Indus., Inc. v. Universal Instruments Corp.*, 1992 U.S. Dist. LEXIS 13458 (N.D.N.Y. Mar. 24, 1992) (defendants' motion for summary judgment of laches denied because presumption of laches had been rebutted); *Northern Telecom, Inc. v. Datapoint Corp.*, 1992 U.S. Dist. LEXIS 8068, 23 USPQ2D (BNA) 1881 (N.D. Tex. June 4, 1992) (after trial to the court, judge rejected the laches defense, holding that the presumption of laches had been rebutted, and that defendant failed to prove the existence of material economic or evidentiary prejudice); and *U.S. Philips Corp. v. Sears Roebuck & Co.*, 1992 U.S. Dist. LEXIS 9390 (N.D. Ill. June 25, 1992) (plaintiffs' motion for summary judgment of no laches or equitable estoppel denied); *Henstreet v. Scan-Optics, Inc.*, 1992 U.S. Dist. LEXIS 18393 (N.D. Ill. Dec. 2, 1992) (same).

91. *Aukerman*, 960 F.2d at 1028, 22 USPQ2D (BNA) at 1325.

92. *Aukerman*, 960 F.2d at 1028, 22 USPQ2D (BNA) at 1325. The Federal Circuit further explained:

The first element of equitable estoppel concerns the statements or conduct of the patentee which must "communicate something in a misleading way." The "something" with which this case, as well as the vast majority of equitable estoppel cases in the patent field is concerned, is that the accused infringer will

that “[c]onduct” may include specific statements, action, inaction, or silence where there was an obligation to speak.”⁹³ While the patentee’s conduct must be “misleading,” it is not necessary that the patentee intended its conduct to mislead.⁹⁴ That is somewhat of a departure from prior cases in which the Federal Circuit had stated that “there is precedent for applying equitable estoppel where there has been ‘intentionally misleading silence’.”⁹⁵

As to misleading conduct through “inaction,” the Federal Circuit explained that “[i]n the most common situation, the patentee specifically objects to the activities currently asserted as infringement in the suit and then does not follow up for years.”⁹⁶ According to the Federal Circuit, there was “ample” precedent “that equitable estoppel may arise where, coupled with other factors, a patentee’s ‘misleading conduct’ is essentially misleading *inaction*.”⁹⁷

“However, plaintiff’s inaction must be combined with other facts respecting the relationship or contacts between the parties to give rise to the necessary inference that the claim against the defendant is abandoned.”⁹⁸ “Delay in filing suit may be evidence which influences the assessment of whether the patentee’s conduct is misleading”⁹⁹ only where it is combined with other factors giving rise to the necessary inference that the claim against the defendant is abandoned. “It is clear, thus, that for equitable estoppel the alleged infringer cannot be unaware — as is possible under laches — of the patentee and/or its patent. The alleged infringer also must

not be disturbed by the plaintiff patentee in the activities in which the former is currently engaged. The patentee’s conduct must have supported an inference that the patentee did not intend to press an infringement claim against the alleged infringer.

960 F.2d at 1042, 22 USPQ2D (BNA) at 1336.

93. *Aukerman*, 960 F.2d at 1028, 22 USPQ2D (BNA) at 1325.

94. The Federal Circuit held that with respect to the case at bar:

Aukerman argued that Chaides had to prove *intentionally* misleading silence. The district court properly rejected *Aukerman*’s argument respecting the need to prove intent to mislead on the basis of *Hottel*, 833 F.2d at 1574-75, 4 USPQ2D at 1941-42. How one characterizes a patentee’s silence is immaterial. Properly focused, the issue here is whether *Aukerman*’s course of conduct reasonably gave rise to an inference in Chaides that *Aukerman* was not going to enforce the ‘133 and ‘633 patents against Chaides.

960 F.2d at 1043, 22 USPQ2D (BNA) at 1337 (emphasis in original) (citation omitted).

95. *Hottel Corp. v. Seaman Corp.*, 833 F.2d 1570, 1572, 4 USPQ2D 1939, 1941 (Fed. Cir. 1987), *overruled by* *A.C. Aukerman v. R.L. Chaides Constr. Co.*, 960 F.2d 1020 (Fed. Cir. 1992).

96. *Aukerman*, 960 F.2d at 1042, 22 USPQ2D (BNA) at 1336.

97. *Aukerman*, 960 F.2d at 1042, 22 USPQ2D (BNA) at 1336 (emphasis in original).

98. *Aukerman*, 960 F.2d at 1042, 22 USPQ2D (BNA) at 1336.

99. *Aukerman*, 960 F.2d at 1042, 22 USPQ2D (BNA) at 1336.

know or reasonably be able to infer that the patentee has known of the former's activities for some time."¹⁰⁰

For that reason, "unreasonable and inexcusable delay" *alone* cannot satisfy this first element. On the other hand, the first element can be met where the misleading conduct is something other than "inaction," such that there is no "unreasonable and inexcusable delay" in filing suit (a laches requirement). Thus, "[d]elay in filing suit . . . is not a requirement of equitable estoppel."¹⁰¹ "Unlike laches, equitable estoppel does not require the passage of an unreasonable period of time in filing suit."¹⁰² Accordingly, while the Federal Circuit had previously stated in *Jamesbury* that equitable estoppel requires "unreasonable and inexcusable delay in filing suit,"¹⁰³ the Federal Circuit held here that "[t]he test set out in *Jamesbury* confusingly intertwines the elements of laches and equitable estoppel and is expressly overruled."¹⁰⁴

*i. Misleading Conduct Through a Charge of
Infringement Followed by Delay in Filing Suit*

As noted above, in respect to misleading conduct through *inaction*, "[i]n the most common situation, the patentee specifically objects to the activities currently asserted as infringement in the suit and then does not follow up for years."¹⁰⁵ Thus, "[i]n the cases that have applied intentionally misleading silence [inaction] in the patent infringement context, a patentee threatened *immediate or vigorous enforcement* of its patent rights but then did nothing for an unreasonably long time."¹⁰⁶ But where "the periods of silence did not follow any communication indicating that it would take *immediate*

100. *Aukerman*, 960 F.2d at 1042, 22 USPQ2D (BNA) at 1336.

101. *Aukerman*, 960 F.2d at 1042, 22 USPQ2D (BNA) at 1336.

102. *Aukerman*, 960 F.2d at 1042, 22 USPQ2D (BNA) at 1336.

103. *Jamesbury Corp. v. Litton Indus. Prod., Inc.*, 839 F.2d 1544, 1553, 5 USPQ2D (BNA) 1779, 1786 (Fed. Cir. 1988), *overruled by* A.C. *Aukerman v. R.L. Chaides Constr. Co.*, 960 F.2d 1020 (Fed. Cir. 1992).

104. *Aukerman*, 960 F.2d at 1042, 22 USPQ2D (BNA) at 1336.

105. *Aukerman*, 960 F.2d at 1042, 22 USPQ2D (BNA) at 1336.

106. *Hottel Corp. v. Seaman Corp.*, 833 F.2d 1570, 1574, 4 USPQ2D (BNA) 1939, 1941 (Fed. Cir. 1987) (citations omitted) (emphasis added), *overruled by* A.C. *Aukerman v. R.L. Chaides Constr. Co.*, 960 F.2d 1020 (Fed. Cir. 1992). *See also Jamesbury*, 839 F.2d at 1555, 5 USPQ2D (BNA) at 1787 (patentee charged defendant with infringement; defendant asserted that it did not infringe the patent; patentee told defendant its attorney was considering the matter carefully; patentee then waited eight years before filing suit; Federal Circuit affirmed district court's grant of summary judgment of estoppel, concluding that: "Jamesbury's silence in the face of its obligation to inform Contromatics of the result of its consideration reasonably could have led Contromatics to conclude either that Jamesbury had determined that Contromatics was not infringing or that it would ignore the infringement.").

action, which if not followed up might indicate that [the patentee] had dropped the matter," such conduct is insufficient to support an equitable estoppel defense.¹⁰⁷

In *Aukerman* there was no threat of "immediate or vigorous enforcement" by the patentee prior to the long period of silence. Instead, the correspondence in 1979 merely stated that the patentee was seeking to enforce its patents against all infringers, and that it would waive liability for past infringement if the defendant accepted a license by June 1, 1979.¹⁰⁸ Thus, one would have thought that the inaction was not of the type sufficient to support an equitable estoppel defense. Nevertheless, the district court granted summary judgment of estoppel and, while the Federal Circuit reversed, it did not mention the lack of a threat of "immediate or vigorous enforcement" as the reason for the reversal. Indeed, the Federal Circuit said that the defendant could reasonably infer from the charge of infringement and the patentee's eight year silence after the defendant responded that the infringement problem was Gomaco's and that the infringement was in any event *de minimis*, "that by remaining silent Aukerman abandoned its claim against Chaides."¹⁰⁹ Thus, it appears that the Federal Circuit has relaxed somewhat the standard for estoppel. There is no longer what appeared to have been an absolute requirement that the threat be of "immediate and vigorous" enforcement.

As it had with respect to the laches defense, the patentee argued "that the delay is excused by reason of litigation against others, even though Chaides was not informed of the litigation."¹¹⁰ The Federal Circuit rejected that argument here, as to estoppel, even though it had accepted that argument before as to laches, stating:

Aukerman argues that the delay is excused by reason of litigation against others, even though Chaides was not informed of the litigation. However, that argument is off the mark. A party must generally notify an accused infringer about other litigation for it

107. *Hottel*, 833 F.2d at 1574, 4 USPQ2D (BNA) at 1942 (emphasis added) (summary judgment of laches affirmed; summary judgment of estoppel reversed). See also *Meyers v. Asics Corp.*, 974 F.2d 1304, 1309, 24 USPQ2D (BNA) 1036, 1039 (Fed. Cir. 1992) (*Meyers-II*) (post-*Aukerman* case in which the Federal Circuit reversed the district court's grant of summary judgment of equitable estoppel because "[t]he defendants have not shown that [plaintiff] Meyers threatened immediate and vigorous enforcement of his patents and then by silence lulled them into the belief that he did not intend to enforce his patents.").

108. *Aukerman*, 960 F.2d at 1026, 22 USPQ2D (BNA) at 1323.

109. *Aukerman*, 960 F.2d at 1044, 22 USPQ2D (BNA) at 1337.

110. *Aukerman*, 960 F.2d at 1044, 22 USPQ2D (BNA) at 1337.

to impact the defense of equitable estoppel.¹¹¹ This 'requirement' is a matter of logic. Other litigation can not logically enter into whether Chaides reasonably drew an inference that it would not be sued if such facts are not known to Chaides.¹¹²

In other words, what the subjective reasons the patentee has for not suing the infringer are irrelevant to a determination of whether the patentee's overt actions towards the defendant were of the type which would "[lead] the alleged infringer to reasonably infer that the patentee does not intend to enforce its patent against the alleged infringer."¹¹³

As noted above, the Federal Circuit found that one reasonable inference to be drawn from plaintiff's eight year delay following defendant's assertion that the infringement was *de minimis* and Gomaco's problem was that "Aukerman abandoned its claim against Chaides."¹¹⁴ Nevertheless, the Federal Circuit also found that an alternative reasonable inference was that Aukerman was *only* abandoning its claim as to *de minimis* infringement, not any claim should the infringement multiply so as to become quite substantial.¹¹⁵ The district court on summary judgment was required to accept the inference most favorable to plaintiff. But, instead, the district court accepted the inference most favorable to the defendant. That was error and the summary judgment was therefore

111. It should be appreciated that the cases cited by the Federal Circuit — *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 877, 20 USPQ2D (BNA) 1045, 1050 (Fed. Cir. 1991); *Hottel*, 833 F.2d at 1573, 4 USPQ2D (BNA) at 1940-41; and *Studiengesellschaft Kohle mbH v. Eastman Kodak Co.*, 616 F.2d 1315, 1330, 206 USPQ (BNA) 577, 591 (5th Cir. 1980), *cert. denied*, 449 U.S. 1014 (1980) — do not support the Federal Circuit's conclusion. In both *Vaupel* and *Hottel* the Federal Circuit spoke of the need for notice to the infringer *only* with respect to the laches defense, not the estoppel defense. As noted above, the Federal Circuit in *Aukerman* removed the absolute requirement of notice in connection with the laches defense. Now it is, for the first time, indicating that an excuse or reason for not suing which is not made known to the infringer cannot be applied to defeat an equitable estoppel defense. In *Studiengesellschaft Kohle*, 616 F.2d at 1330, 206 USPQ at 591, the Fifth Circuit reversed the district court's finding of laches and estoppel in part because there was adequate notice of the other litigation and intent to sue when that litigation was completed.

112. *Aukerman*, 960 F.2d at 1044, 22 USPQ2D (BNA) at 1337 (citations omitted).

113. *Aukerman*, 960 F.2d at 1028, 22 USPQ2D (BNA) at 1325.

114. *Aukerman*, 960 F.2d at 1044, 22 USPQ2D (BNA) at 1337.

115. The Federal Circuit stated:

While the above factors favor the nonenforcement inference, Chaides' further statement that Aukerman would only recover \$200-\$300 a year could lead one in Chaides' position to infer that Aukerman did not sue because the amount in issue was *de minimis*, not that Aukerman was abandoning its claim against Chaides for all time regardless of quantum. At most Aukerman could merely have been waiving an infringement claim for \$ 300.00 per year.

960 F.2d at 1044, 22 USPQ2D (BNA) at 1337-38.

reversed.¹¹⁶

The moral of the story is simple. If you try to dissuade a plaintiff from suing based on the minimal nature of the infringement, the result may be a decision by the plaintiff not to file suit until your infringement becomes substantial. But when the plaintiff does sue, you may have no equitable estoppel defense. The jury might accept an inference that plaintiff's conduct only indicated an intent not to sue so long as your infringement remained *de minimis*. On the other hand, if you respond to an infringement charge only with an assertion that the patent at issue is invalid, unenforceable and/or noninfringed, the aforesaid inference would not be reasonable in the event the plaintiff elects not to sue without further communication. The only reasonable inference would then appear to be that the plaintiff abandoned its claim against you in its entirety because of your challenge to the merits of the infringement claim. Of course, if you do not raise the minimal nature of the infringement, the plaintiff might sue you notwithstanding your protestations about the strength of the patent infringement claim. Thus, no response to an infringement charge should be lightly made. All the possible outgrowths from that response should first be examined.

b. Reliance by the Infringer on the Misleading Conduct

The second element of equitable estoppel is reliance “[t]he accused infringer must show that, in fact, it substantially relied on the misleading conduct of the patentee in connection with taking some action.”¹¹⁷ “To show reliance, the infringer must have had a relationship or communication with the plaintiff which lulls the infringer into a sense of security in going ahead with building the plant.”¹¹⁸

c. Prejudice to the Infringer Caused by His Reliance on the Misleading Conduct

The third element of an equitable estoppel defense is that of prejudice to the defendant “[d]ue to its reliance, the alleged infringer will be materially prejudiced if the patentee is allowed to

116. *Aukerman*, 960 F.2d at 1044, 22 USPQ2D (BNA) at 1338 (“In view of the different inferences which could be drawn from the exchange of correspondence, it is clear that the court drew an unfavorable inference against Aukerman. That is impermissible on summary judgment.”).

117. *Aukerman*, 960 F.2d at 1042-43, 22 USPQ2D (BNA) at 1336-37.

118. *Aukerman*, 960 F.2d at 1043, 22 USPQ2D (BNA) at 1337.

proceed with its claim.”¹¹⁹ “As with laches, the prejudice may be a change of economic position or loss of evidence.”¹²⁰

2. *Don't Confuse the Second and Third Elements*

The Federal Circuit cautioned that the second and third elements — reliance and prejudice — should not be confused. There must be reliance (which is a requirement of estoppel, but not laches) which causes the prejudice:

The second element, reliance, is not a requirement of laches but is essential to equitable estoppel. The accused infringer must show that, in fact, it substantially relied on the misleading conduct of the patentee in connection with taking some action. Reliance is not the same as prejudice or harm, although frequently confused. An infringer can build a plant being entirely unaware of the patent. As a result of infringement, the infringer may be unable to use the facility. Although harmed, the infringer could not show reliance on the patentee's conduct. To show reliance, the infringer must have had a relationship or communication with the plaintiff which lulls the infringer into a sense of security in going ahead with building the plant.¹²¹

3. *No Presumption of Estoppel*

The Federal Circuit reaffirmed its prior holdings that, unlike laches, there is no presumption of equitable estoppel, even where the “misleading conduct” included an unreasonable and inexcusable delay of more than six years in filing suit.¹²²

119. *Aukerman*, 960 F.2d at 1028, 22 USPQ2D (BNA) at 1325.

120. *Aukerman*, 960 F.2d at 1043, 22 USPQ2D (BNA) at 1337.

121. *Aukerman*, 960 F.2d at 1042-43, 22 USPQ2D (BNA) at 1336-37 (citation omitted). In *Meyers v. Asics Corp.*, 974 F.2d 1304, 24 USPQ2D (BNA) 1036 (Fed. Cir. 1992) (*Meyers-II*), the Federal Circuit reversed the district court's grant of summary judgment of laches and equitable estoppel and, in so doing, reiterated that: “[D]efendants need not show that they relied on [plaintiff] Meyers' delay to establish laches. However, they must show that the prejudice they suffered resulted from the delay.” 974 F.2d at 1308 n.1, 24 USPQ2D (BNA) at 1038 n.1.

122. The Federal Circuit explained:

Another significant difference from laches is that no presumption adheres to an equitable estoppel defense. Despite a six-year delay in suit being filed, a defendant must prove all of the factual elements of estoppel on which the discretionary power of the court rests. The reasons for this are two-fold. First, the presumed laches factors, that is, unreasonable and inexcusable delay and prejudice resulting therefrom are not elements of estoppel. Second, the relief granted in estoppel is broader than in laches. Because the whole suit may be barred, we conclude that the defendant should carry a burden to establish the defense based on proof, not a presumption.

960 F.2d at 1043, 22 USPQ2D (BNA) at 1337.

V. OTHER EQUITABLE CONSIDERATIONS WHICH MAY DEFEAT A LACHES DEFENSE OR AN ESTOPPEL DEFENSE, EVEN A PRESUMPTIVE LACHES DEFENSE

The Federal Circuit explained that, even where the two elements (factors) of a laches defense are met (undue delay and prejudice), a laches defense may be rejected because it is an equitable defense, committed to the sound discretion of the trial judge based on his consideration of the totality of the circumstances:

The application of the defense of laches is committed to the sound discretion of the district court. With its origins in equity, a determination of laches is not made upon the application of "mechanical rules." The defense, being personal to the particular party and equitable in nature, must have flexibility in its application. A court must look at all of the particular facts and circumstances of each case and weigh the equities of the parties.¹²³

The district court should consider [whether the patentee's delay in bringing the suit was unreasonable and inexcusable, whether the alleged infringer suffered material prejudice attributable to the delay] and all of the evidence and other circumstances to determine whether equity should intercede to bar pre-filing damages.¹²⁴

A patentee may also defeat a laches defense if the infringer "has engaged in particularly egregious conduct which would change the equities significantly in plaintiff's favor." Conscious copying may be such a factor weighing against the defendant, whereas ignorance or a good faith belief in the merits of a defense may tilt matters in its favor.¹²⁵

Thus, for laches, the length of delay, the seriousness of prejudice, the reasonableness of excuses, and the defendant's conduct or culpability must be weighed to determine whether the patentee dealt unfairly with the alleged infringer by not promptly bringing suit. In sum, a district court must weigh all pertinent facts and equities in making a decision on the laches defense.¹²⁶

The Federal Circuit explained that even if the presumption of laches cannot be rebutted, laches may not be found:

Even if unable to overcome the presumption, a patentee may be able to preclude application of the laches defense with proof that the accused infringer was itself guilty of misdeeds towards

123. *Aukerman*, 960 F.2d at 1032, 22 USPQ2D (BNA) at 1328 (citations omitted).

124. *Aukerman*, 960 F.2d at 1028, 22 USPQ2D (BNA) at 1324-25.

125. *Aukerman*, 960 F.2d at 1033, 22 USPQ2D (BNA) at 1329 (citations omitted).

126. *Aukerman*, 960 F.2d at 1034, 22 USPQ2D (BNA) at 1329.

the patentee. This flows from the maxim, "He who seeks equity must do equity."¹²⁷

Thus, the presumption does not require a finding of laches in every case:

It must be emphasized that the establishment of the factors of undue delay and prejudice, whether by actual proof or by the presumption, does not *mandate* recognition of a laches defense in every case. Laches remains an equitable judgment of the trial court in light of all the circumstances. Laches is not *established* by undue delay and prejudice. Those factors merely lay the foundation for the trial court's exercise of discretion. Where there is evidence of other factors which would make it inequitable to recognize the defense despite undue delay and prejudice, the defense may be denied.¹²⁸

The Federal Circuit then explained that, like laches, the existence of the essential elements of an equitable estoppel defense does not mandate a holding that the defense is present:

Finally, the trial court must, even where the three elements of equitable estoppel are established, take into consideration any other evidence and facts respecting the equities of the parties in exercising its discretion and deciding whether to allow the defense of equitable estoppel to bar the suit.¹²⁹

1. *Copying as the Most Common Equitable Factor Defeating a Laches or Equitable Estoppel Defense*

Knowingly (or deliberately or intentionally) copying a patented product from the product in the marketplace, or from the patent describing the product, is "egregious conduct" which may be applied to defeat a laches or equitable estoppel defense.¹³⁰ The Federal Circuit affirmed this principle in *Aukerman*, noting that "[c]onscious copying may be such a [equitable] factor weighing against the defendant, whereas ignorance or a good faith belief in

127. *Aukerman*, 960 F.2d at 1038, 22 USPQ2D (BNA) at 1333.

128. *Aukerman*, 960 F.2d at 1036, 22 USPQ2D (BNA) at 1331 (emphasis in original). "A presumption of laches arises where a patentee delays bringing suit for more than six years after the date the patentee knew or should have known of the alleged infringer's activity." 960 F.2d at 1028, 22 USPQ2D (BNA) at 1325.

129. *Aukerman*, 960 F.2d at 1043, 22 USPQ2D (BNA) at 1337.

130. *Bott v. Four Star Corp.*, 807 F.2d 1567, 1576, 1 USPQ2D 1210, 1217 (Fed. Cir. 1986) ("[W]e hold that Four Star's defense of laches was defeated by its egregious conduct"; the egregious conduct was that defendant "knowingly copied Bott's carrier" and "inexcusably accelerated its infringing sales after this court affirmed the district court's decision on liability.").

the merits of a defense may tilt matters in its favor.”¹³¹ A representative case applying the “egregious conduct” through copying principle is *C.R. Bard Inc. v. Cordis Corp.*¹³²

In *Bard*, Cordis sued Bard for patent infringement in 1979.¹³³ The parties settled with Bard taking a license.¹³⁴ Bard paid royalties until the end of September 1981 when Bard began to sell a new product which it believed did not infringe the Cordis patent.¹³⁵ Bard wrote Cordis a letter in January 1982 stating that no royalties were required because Bard’s in-house patent counsel had concluded that the new product was noninfringing.¹³⁶ With the letter, Bard provided a sample of the new product for Cordis’ consideration.¹³⁷ Cordis ignored the Bard letter.¹³⁸ Nevertheless, seven years later, in January of 1989, Cordis accused Bard of infringement and breach of the license agreement for failing to pay royalties on the new product.¹³⁹ Bard filed an action for declaratory relief and Cordis counterclaimed for patent infringement. Bard moved for summary judgment on its laches defenses which the district judge denied.

The district court noted that it was undisputed that while Cordis should have known of Bard’s alleged infringement in January 1982 when it received Bard’s letter and a sample product, Cordis delayed seven years before filing its counterclaim for infringement.¹⁴⁰ Thus, the delay of more than six years gave rise to a presumption of laches.¹⁴¹ The court further held it beyond dispute that Cordis had failed to rebut the laches presumption.¹⁴² Nevertheless, the judge denied Bard’s summary judgment motion because there was an issue of fact as to whether Bard’s conduct was “egregious,” thereby defeating the laches defense.¹⁴³

The alleged evidence of egregiousness was (1) Bard’s failure to secure a competent legal opinion that its product did not infringe

131. *Aukerman*, 960 F.2d at 1033, 22 USPQ2D (BNA) at 1329.

132. 17 USPQ2D (BNA) 1391 (D. Mass. 1990).

133. *Id.* at 1391.

134. *Id.* at 1391-92.

135. *Id.* at 1392.

136. *Id.*

137. *C.R. Bard*, 17 USPQ2D (BNA) at 1392.

138. *Id.*

139. *Id.*

140. *Id.* at 1393-94.

141. *Id.* at 1394.

142. *C.R. Bard*, 17 USPQ2D (BNA) at 1394 (“Cordis offers nothing to rebut either of these presumptions”).

143. *Id.*

the patent before selling it even though it was aware of the patent;¹⁴⁴ (2) testimony by a Bard engineer that the primary goal in designing the new product was avoiding the patent;¹⁴⁵ (3) Bard's access to the patent and the patentee's product while designing its product;¹⁴⁶ and (4) Bard's operating under the license as to its prior product which Bard's engineers conceded was covered by the patent claims.¹⁴⁷ The trial court essentially equated "egregious conduct" sufficient to defeat a laches defense with "willful infringement" sufficient to allow the court to "increase the damages up to three times the amount found or assessed"¹⁴⁸ under 35 U.S.C. § 284.¹⁴⁹ That is, the trial court denied summary judgment of laches, concluding that "it is certainly an issue of fact whether Bard willfully infringed the Stevens patent and engaged in egregious conduct."¹⁵⁰

144. *Id.* Apparently Cordis argued that the opinion of Bard's in-house counsel was not "competent."

145. *Id.* This is a curious factor cited as evidence of "egregious" conduct, since it is settled law that one can avoid infringement by intentionally designing a product so that it falls outside the scope of a patent's claims; indeed, the "negative incentive" to "design around" a patent is encouraged, not discouraged, because that "bring[s] a steady flow of innovations to the marketplace." *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236, 224 USPQ (BNA) 418, 424 (Fed. Cir. 1985). Moreover, when such "design around" attempts are unsuccessful and infringement is in fact not avoided, the good faith design around attempt is a factor favoring a finding that the infringement was not "willful" and that the actions of the defendant were not "egregious." 751 F.2d at 1236, 224 USPQ (BNA) at 424. See also *Spindelfabrik Suessen-Schurr, Stahlecker & Grill gmbH v. Schubert & Salzer Maschinenfabrik Aktiengesellschaft*, 829 F.2d 1075, 1084, 4 USPQ2D 1044, 1051 (Fed. Cir. 1987) ("We have noted a good faith effort to 'design around' as indicating support for a non-willful finding."), *cert. denied*, 484 U.S. 1063 (1988).

146. *C.R. Bard*, 17 USPQ2D (BNA) at 1394.

147. *Id.*

148. 35 U.S.C. § 284 (1988).

149. *Modine Mfg. Co. v. Allen Group, Inc.*, 917 F.2d 538, 543, 16 USPQ2D (BNA) 1622, 1625 (Fed. Cir. 1990) (a finding of "willful infringement" authorizes, but does not mandate an award of increased damages under 35 U.S.C. § 284).

150. *C.R. Bard*, 17 USPQ2D (BNA) at 1394. Bard also moved for summary judgment on its equitable estoppel defense. Under *Aukerman*, the same conduct which defeated the motion relative to laches should also have defeated the estoppel defense. However, the trial judge, relying on pre-*Aukerman* precedent, rejected the equitable estoppel motion on other grounds. The judge held that Cordis' silence in response to Bard's activity in January 1982 was "not affirmative conduct by the patent holder [which] has induced the belief that it has abandoned its claim against the infringer" since "silence alone, unless it is intentionally misleading, is not sufficient affirmative conduct to support an estoppel." *Id.* That was error. As the Federal Circuit explained in *Aukerman*:

Aukerman argued that Chaides had to prove *intentionally* misleading silence. The district court properly rejected Aukerman's argument respecting the need to prove intent to mislead on the basis of *Hottel*, 833 F.2d at 1574-75, 4 USPQ2D at 1941-42. How one characterizes a patentee's silence is immaterial. Properly focused, the issue here is whether Aukerman's course of conduct reasonably gave rise to an inference in Chaides that Aukerman was not going to enforce the '133 and '633 patents against Chaides.

2. *Burdens Re Copying as an Equitable Factor Defeating A Laches or Equitable Estoppel Defense on Summary Judgment*

Access to the patent or the patented product when the accused device is developed may give rise to a presumption of copying, shifting the burden to the defendant to show independent creation in order to avoid a finding of egregious conduct.¹⁵¹ In *Aukerman*, the Federal Circuit applied a variation of this presumptive principle with respect to a motion for summary judgment of estoppel.

In *Aukerman*, both parties used the term "copy" to describe the accused device. Moreover, the defendant's principal testified that he could not remember any differences between the original and the copy except in size.¹⁵² Thus, "[plaintiff] Aukerman argued that [defendant] Chaides was guilty of inequity by building a 'copy' of the [patented] mold."¹⁵³ According to the Federal Circuit, "for purposes of summary judgment, Chaides' copying should have been deemed misconduct to be weighed into the court's decision, but it was not."¹⁵⁴ Instead, the district court erroneously placed the *additional* burden on plaintiff to produce evidence that the "copy" infringed the claim in order to raise the "egregious conduct" element to defeat the motion for summary judgment.¹⁵⁵ Since *Aukerman* produced no evidence demonstrating "how the copy infringed the patents," summary judgment was proper.¹⁵⁶ That was error according to the Federal Circuit. There was no such *additional* requirement.¹⁵⁷

960 F.2d at 1043, 22 USPQ2D (BNA) at 1337 (emphasis in original) (citation omitted).

151. *TWM Mfg. Co. Inc. v. Dura Corp.*, 722 F.2d 1261, 1268-69, 221 USPQ (BNA) 25, 30 (6th Cir. 1983) (borrowing this concept of burden shifting from the laches defense as applied in the copyright law). See also *Bott*, 807 F.2d at 1576, 1 USPQ2D at 1217 (Federal Circuit discussed *TWM*'s holding regarding burden shifting without expressly adopting or rejecting it).

152. *Aukerman*, 960 F.2d at 1044, 22 USPQ2D (BNA) at 1338.

153. *Aukerman*, 960 F.2d at 1044, 22 USPQ2D (BNA) at 1338.

154. *Aukerman*, 960 F.2d at 1044, 22 USPQ2D (BNA) at 1338.

155. *Aukerman*, 960 F.2d at 1044, 22 USPQ2D (BNA) at 1338.

156. *Aukerman*, 960 F.2d at 1044, 22 USPQ2D (BNA) at 1338.

157. The Federal Circuit also stated that the evidence showing that the accused product was a "copy" actually shifted the burden to the defendant to prove, without dispute of material fact and resolving all issues and inferences in plaintiff's favor, that the "copy" did not infringe the patent. 960 F.2d at 1044, 22 USPQ2D (BNA) at 1338. If plaintiff proved this, there would be no egregious conduct. But there would also be no infringement, a separate defense from estoppel. Here the testimony of the product as a "copy," at least when coupled with the testimony of defendant's principal that he could not remember any differences between the original and the copy except in size, created an inference of infringement. The district court erred in discounting this inference, requiring plaintiff to produce evidence demonstrating "how the copy infringed the patents."

VI. LACHES AND ESTOPPEL APPLIED TO THE *AUKERMAN* FACTS

The Federal Circuit concluded that it must reverse the district court's grant of summary judgment of laches and equitable estoppel.¹⁵⁸

Reversal of the laches holding was required because of three fundamental errors made by the district court in granting summary judgment. First, the lower court improperly used the laches presumption to shift the ultimate burden of persuasion (proof) to the patentee to prove that its more than six year delay in filing suit was reasonable and excusable, rather than shifting only the burden of coming forward.¹⁵⁹ Second, the trial court incorrectly made an absolute requirement of the "other litigation" excuse, that the patentee provide notice to the infringer of the reason that the patentee delayed in filing suit.¹⁶⁰ Third, the court erred in rejecting the *de minimis* infringement excuse on summary judgment, since inferences most favorable to the patentee would be that the insubstantial infringement, under the totality of the circumstances, excused the delay at least until the patentee knew or should have known that the infringement was substantial, and that the patentee did not delay unduly after it knew or should have known that the infringement was substantial.¹⁶¹

As to equitable estoppel, reversal was necessary in light of two basic errors made by the district court in granting summary judgment. First, a reasonable inference favorable to plaintiff to be drawn from plaintiff's eight year delay following defendant's assertion that the infringement was *de minimis* and Gomaco's problem, was that Aukerman was *only* abandoning its claim as to *de minimis* infringement, not any claim should the infringement multiply so as to become quite substantial.¹⁶² The district court erred in accepting a contrary inference, more favorable to the defendant, that Aukerman was completely abandoning its infringement claim against the defendant.¹⁶³ Second, the district court erred in requiring the plaintiff to produce evidence of infringement in order to de-

158. *Aukerman*, 960 F.2d at 1044, 22 USPQ2D (BNA) at 1338 ("We conclude that summary judgment, holding that Aukerman was equitably estopped from assertion of infringement against Chaides, was improperly granted and is reversed. The issue is remanded for trial.").

159. *Aukerman*, 960 F.2d at 1039, 22 USPQ2D (BNA) at 1334.

160. *Aukerman*, 960 F.2d at 1039, 22 USPQ2D (BNA) at 1334.

161. *Aukerman*, 960 F.2d at 1039, 22 USPQ2D (BNA) at 1334.

162. *Aukerman*, 960 F.2d at 1044, 22 USPQ2D (BNA) at 1337-38.

163. *Aukerman*, 960 F.2d at 1044, 22 USPQ2D (BNA) at 1338.

feat the motion for summary judgment.¹⁶⁴ Proof that the accused product was a “copy” of plaintiff’s product is without more sufficient evidence of egregious conduct to defeat a motion for summary judgment on the equitable estoppel defense.¹⁶⁵

VII. CONCLUSION

In the present climate of enormous damage awards, patent owners are dusting off and scrupulously studying their patent portfolios for patents which may be infringed. Often a potential infringement is unearthed and a belated, sometimes more than a decade belated, infringement claim is made. Occasionally, the would-be infringement arises from use of technology adopted and used by an entire industry of manufacturers, which have thus made the technology an industry standard. Until recently, laches and equitable estoppel were two of the most potent defenses to such belated charges of patent infringement. Moreover, again until recently, summary judgment as to one or both of these defenses was not an uncommon occurrence. With one swift stroke of the pen, the Federal Circuit in *Aukerman* has drastically limited the availability of these two defenses, and all but eliminated their application by an accused infringer on summary judgment. The *Aukerman* case should thus be studied and carefully considered before placing too heavy a reliance on these defenses in opposition to a charge of patent infringement.

164. *Aukerman*, 960 F.2d at 1044, 22 USPQ2D (BNA) at 1338.

165. *Aukerman*, 960 F.2d at 1044, 22 USPQd (BNA) at 1338.

PATENT LAW DEVELOPMENTS IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DURING 1991

Alex Chartove*

I. NOVELTY - 35 U.S.C. § 102

A. *Extrinsic Evidence may be Considered to Explain the Meaning of a Reference under 35 U.S.C. § 102*

The subject patent in the case of *Scripps Clinic & Research Foundation v. Genentech, Inc.*¹ was a reissue patent entitled "Ultrapurification of Factor VIII Using Monoclonal Antibodies."² Before the district court, the accused infringer had argued that several claims of the patent were invalid under 35 U.S.C. § 102(b) based upon subject matter described in a 1979 publication by a Dr. Harris.³ The parties had filed three successive declarations of Dr. Harris with the district court, each declaration explaining the meaning of the 1979 publication.

The district court, citing the third Harris declaration, held that the claims were invalid under 35 U.S.C. § 102(b) in view of the 1979 Harris publication and granted the accused infringer's motion for summary judgment on this issue.⁴ The patentee appealed.

On appeal, the Federal Circuit observed that it is sometimes appropriate to consider extrinsic evidence to explain the meaning of a reference under 35 U.S.C. § 102.⁵ It is appropriate to use the extrinsic evidence to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, but it is not appropriate to use the extrinsic evidence to fill gaps in the reference.⁶

In *Scripps*, the record showed apparent inconsistencies among

Copyright © 1993 by Alex Chartove.

* B.A. Brandeis University; J.D. Duke University. Mr. Chartove is a partner in the law firm of Spensley Horn Juba & Lubitz, Washington, D.C.

1. 927 F.2d 1565, 18 USPQ2D 1001 (Fed. Cir. 1991).

2. *Id.* at 1003.

3. *Id.* at 1010.

4. *Id.*

5. *Id.*

6. See *Studiengesellschaft Kohle, mbH v. Dart Industries, Inc.*, 726 F.2d 724, 727, 220 USPQ 841, 842 (Fed. Cir. 1984).

the three Harris declarations.⁷ To the extent that these apparent inconsistencies raised questions of credibility and weight, whether of the witness or of the interpretation of the publication, such factual questions were not properly resolved on summary judgment. The Federal Circuit therefore reversed the grant of partial summary judgment of invalidity for anticipation by the Harris publication.⁸

B. Invalidity Under 35 U.S.C. § 102(b) Requires Proof by Clear and Convincing Evidence

The respondent in the case of *Intel Corporation v. U. S. International Trade Commission*⁹ had argued that the subject patent was invalid under 35 U.S.C. § 102(b) because devices which embodied the patented invention had been placed on sale more than one year before the patent application's filing date.¹⁰

On appeal, the Federal Circuit noted that the respondent had not offered any direct or circumstantial evidence showing that the patentee had sold the patented invention before the critical date. Instead, the respondent had merely offered evidence showing that such a sale had been "likely", and had argued that the fact of such sale could be reasonably inferred from the evidence.¹¹

The Federal Circuit found that the reasonable inferences which the respondent suggested be drawn from the evidence did not meet the "clear and convincing" standard of proof required for showing patent invalidity under 35 U.S.C. § 102(b).¹² Thus, the respondent had failed to carry its burden of proof that a sale or offer to sell had been made prior to the critical date. Accordingly, the Federal Circuit affirmed the Commission's determination that the patent was not proven invalid.¹³

C. Post-Critical Date Events May Be Used to Establish That An Invention Was "On Sale" Under 35 U.S.C. § 102(b)

The application for the subject patent in the case of *Sonoscan, Inc. v. Sonotek, Inc.*¹⁴ had been filed on September 15, 1988. On

7. *Scripps Clinic & Research Foundation v. Genentech, Inc.*; 18 USPQ2D 1001, 1004 (Fed. Cir. 1991).

8. *Id.* at 1016.

9. 946 F.2d 821, 20 USPQ2D 1161 (Fed. Cir. 1991).

10. *Id.* at 1169.

11. *Id.*

12. *Id.*

13. *Id.*

14. 936 F.2d 1261, 19 USPQ2D 1156 (Fed. Cir. 1991).

September 10, 1987 (more than one year prior to the application filing date) the patentee had quoted a price on a system including the claimed invention to a first customer.¹⁵ On September 18, 1987 (less than one year prior to the application filing date) the patentee had quoted the same price on the same system to a second customer.¹⁶

After the patent issued, the patentee filed suit against an alleged infringer. As an affirmative defense, the alleged infringer asserted that the patent was invalid under 35 U.S.C. § 102(b) on the basis that the claimed invention had been on sale more than one year prior to the patent application filing date.

The patentee conceded that the September 18 quotation to the second customer had been for the claimed invention, but argued that on the September 15 "critical date" the invention had not been sufficiently developed to be "on sale."¹⁷

The district court heard testimony concerning the state of development of the invention both before and after the September 15 "critical date." The district court found that no serious change in the invention had taken place between September 10 and September 18.¹⁸

On the basis of these findings, the district court concluded that the claimed invention had been sufficiently developed so that the September 10 quotation was a genuine offer to sell the claimed invention.¹⁹ The district court therefore held the patent invalid under § 102(b) and entered final judgment in favor of the alleged infringer.²⁰ The patentee appealed.

On appeal, the patentee argued that the September 18 quotation was irrelevant because it had occurred after the critical date, and that the district court had therefore erred by taking the September 18 quotation into consideration.²¹

The Federal Circuit found, however, that the district court had properly inquired as to what was offered in the September 18 quotation, what development activities occurred between September 10 and September 18, and had properly inferred from the evidence that what was adequately developed on September 18 was also adequately developed on September 10. The Federal Circuit therefore

15. *Id.* at 1157.

16. *Id.*

17. *Id.* at 1158.

18. *Id.* at 1159.

19. *Sonoscan*, 19 USPQ2D at 1158.

20. *Sonoscan, Inc. v. Sonotek, Inc.*, 17 USPQ2D 1247 (E.D. Va. 1990).

21. *Sonoscan*, 19 USPQ2D at 1159.

affirmed the judgment of the district court.²²

D. *"Inherency" Represents An Exception to The Rule That Anticipation Requires Every Element of the Claims to Appear in A Single Reference*

The subject patent in the case of *Continental Can Company USA, Inc. v. Monsanto Company*²³ was directed to a plastic bottle whose ribbed bottom structure had sufficient flexibility to impart improved impact resistance, combined with sufficient rigidity to resist deformation under internal pressure. All of the claims recited that the patented plastic bottle was "characterized by the feature that the ribs are hollow."²⁴

The alleged infringer had moved for summary judgment of invalidity under 35 U.S.C. § 102(a) based upon a prior art reference to Marcus.²⁵ The Marcus reference did not state that the ribs disclosed therein were "hollow."²⁶ The alleged infringer had argued, however, that the Marcus ribs were formed by injection blow molding, which was the same process described for the patented ribs. Therefore, according to the alleged infringer, the ribs of the Marcus reference were "inherently" hollow, regardless of how the ribs were shown in the Marcus reference.²⁷

The district court agreed with the alleged infringer, found that all of the claims of the patent were anticipated by the Marcus reference, and granted summary judgment of patent invalidity. The patentee appealed.

On appeal, the Federal Circuit observed that the concept of "inherency" represents a modest flexibility in the rule that anticipation under § 102 requires every element of the claims to appear in a single reference. "Inherency" is not a substitute for determination of patentability under § 103.²⁸ Instead, "inherency" is intended to accommodate those situations in which the common knowledge of the skilled artisan is not expressly stated in the reference.²⁹

To serve as an anticipation under § 102 when a reference is silent about the asserted inherent characteristic, the missing description in the reference may be filled by extrinsic evidence. How-

22. *Id.*

23. 948 F.2d 1264, 20 USPQ2D 1746 (Fed. Cir. 1991).

24. *Id.* at 1747.

25. *Id.*

26. *Id.* at 1748.

27. *Id.*

28. *Continental Can*, 20 USPQ2D at 1749.

29. *Id.*

ever, such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency may not be established by mere probabilities or possibilities.³⁰

In *Continental Can*, there was no dispute that the Marcus reference disclosed an injection blow molding process.³¹ However, there was a dispute regarding whether a skilled artisan would recognize this process as necessarily producing "hollow" ribs, as the term "hollow" was used in the patent. The Federal Circuit concluded that this was a genuine dispute of a material fact which required a trial for its resolution. Resolution of this disputed fact adversely to the patentee was improper on summary judgment. The Federal Circuit therefore vacated the grant of summary judgment of anticipation under § 102(a) and remanded the case.³²

E. *Conception of a Genetic Invention Under 35 U.S.C. § 102(g) Requires That the Inventor Be Able to Define the Gene So As to Distinguish It From Other Materials*

The subject patent in the case of *Amgen, Inc., v. Chugai Pharmaceutical Co., Ltd.*³³ was entitled "DNA Sequences Encoding Erythropoietin."³⁴ The patent claims were directed to a "purified and isolated DNA sequence" encoding human EPO. The structure of this DNA sequence had not been known until September of 1983, when the inventor had reduced the claimed invention to practice by cloning the gene.³⁵

The district court had found that the successful identification and isolation of the EPO gene resulted from a probing strategy which used two sets of fully-degenerate cDNA probes of two different regions of the EPO gene to screen a cDNA library.³⁶ The accused infringer had asserted that this successful strategy had first been conceived by a Dr. Fritsch in 1981, and that Fritsch had been diligent until he reduced the claimed invention to practice in May of

30. In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981); *Hansgirk v. Kemmer*, 26 C.C.P.A. 937, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939).

31. *Continental Can*, 20 USPQ2D at 1750.

32. *Id.*

33. 927 F.2d 1200, 18 USPQ2D 1016 (Fed. Cir. 1991).

34. Erythropoietin (EPO) is a protein consisting of 165 amino acids which stimulates the production of red blood cells.

35. *Amgen*, 18 USPQ2D at 1018.

36. *Id.* at 1019.

1984. The accused infringer therefore had argued that the patent claims were invalid under 35 U.S.C. § 102(g) due to Fritsch's prior invention.³⁷

The district court disagreed with the accused infringer and held that the patent claims were valid and had been infringed.³⁸ The accused infringer appealed.

On appeal, the Federal Circuit noted that a gene is a chemical compound.³⁹ Conception of a chemical compound requires that the inventor be able to define the compound so as to distinguish the compound from other materials, and to describe how to obtain the compound.⁴⁰ If an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, then conception is not established until the gene has been isolated and thereby successfully reduced to practice.⁴¹

Therefore, to act as prior art under 35 U.S.C. § 102(g), Fritsch's conception of a process had to be sufficiently specific that one skilled in the relevant art would succeed in cloning the EPO gene. However, the record showed that prior to September of 1983, Fritsch did not have a complete mental conception of a purified and isolated DNA sequence encoding EPO and a method for its preparation, in which the precise identity of the sequence is envisioned. All Fritsch had at that time was an objective to make an invention which he could not then adequately describe or define sufficiently to distinguish it from other genes. Fritsch had a goal of obtaining the isolated EPO gene and an idea of a possible method of obtaining it, but he did not conceive a purified and isolated DNA sequence encoding EPO and a viable method for obtaining it until after the inventor.⁴²

The record indicated that neither party had an adequate conception of the DNA sequence until reduction to practice had been achieved, and the inventor had been the first to accomplish that goal.

The Federal Circuit concluded that the district court had not erred in finding that the claims directed to a purified and isolated DNA sequence encoding human EPO were not invalidated under

37. *Id.*

38. *Amgen Inc. v. Chugai Pharmaceutical Co.*, 13 USPQ2D 1737 (1990).

39. *Amgen*, 18 USPQ2D at 1021.

40. *Oka v. Youssefieh*, 849 F.2d 581, 583, 7 USPQ 1169, 1171 (Fed. Cir. 1988).

41. *Amgen*, 18 USPQ2D at 1021.

42. *Id.*

35 U.S.C. § 102(g) by the work of Fritsch.⁴³

II. OBVIOUSNESS - 35 U.S.C. § 103

A. *Obviousness Is Not Negated by the Quantity of References Cited*

The claimed invention in the case of *In re Gorman*⁴⁴ was directed to a composite candy sucker on a stick, molded in an elastomeric mold in the shape of a human thumb. All of the claims had been rejected as obvious under 35 U.S.C. § 103 in view of thirteen references.⁴⁵

On appeal, the applicant argued that when it is necessary to combine the teachings of a large number of references in order to support a rejection for obviousness under 35 U.S.C. § 103, this in and of itself weighs against a holding of obviousness.⁴⁶

The Federal Circuit noted, however, that the criterion for obviousness under 35 U.S.C. § 103 is not the number of references, but what the references would have meant to a person of ordinary skill in the field of the invention.⁴⁷

The Federal Circuit found that each element of the claimed invention was present in the prior art, and that the prior art used the various elements for the same purposes as in the claimed invention. These facts made the claimed invention, as a whole, obvious in terms of 35 U.S.C. § 103, and the obviousness of the claimed invention was not negated by the large number of references cited. The rejection of the claims under 35 U.S.C. § 103 was therefore affirmed.⁴⁸

B. *Obviousness Rejection Requires Consideration of the Degree to Which One Reference Might Discredit Another Reference*

The subject application in the case of *In re Young*⁴⁹ was directed to a method and apparatus for generating an acoustic pulse

43. *Id.* at 1022.

44. 933 F.2d 982, 18 USPQ2D 1885 (Fed. Cir. 1991).

45. *Id.* at 1887.

46. *Id.* at 1888.

47. See, *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1383, 231 USPQ 81, 93 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947, 94 L. Ed. 2d 792, 107 S. Ct. 1606 (1987); *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1149, 219 USPQ 857, 860 (Fed. Cir. 1983); *In re Troiel*, 47 C.C.P.A. 795, 274 F.2d 944, 947, 124 USPQ 502, 504 (CCPA 1960); *In re Miller*, 34 C.C.P.A. 910, 159 F.2d 756, 758-59, 72 USPQ 512, 514-15 (CCPA 1947).

48. *Gorman*, 18 USPQ2D at 1889.

49. 927 F.2d 588, 18 USPQ2D 1089 (Fed. Cir. 1991).

in water. All of the claims had been rejected as obvious under 35 U.S.C. § 103 in view of a prior art patent to Carlisle. The Carlisle reference taught both the method and the advantages of the applicant's claimed invention.⁵⁰

The applicant had argued that the teachings of Carlisle had been expressly discredited by a prior art article written by Knudsen. The Knudsen article described a series of tests which evaluated the Carlisle technique. The Knudsen article stated that the Carlisle technique yielded no appreciable improvement in bubble oscillation suppression.⁵¹

The applicant had argued that the effective teaching of the Knudsen/Carlisle combination suggested avoidance of the Carlisle technique, and that a person of ordinary skill in the art would therefore not have considered Carlisle when developing a method and apparatus for generating an acoustic pulse in water. The Board had rejected the applicant's arguments, holding that Carlisle was appropriately applied notwithstanding the teachings of Knudsen.⁵²

On appeal, the issue was whether the Board had properly affirmed the rejection over Carlisle in light of Knudsen's allegedly contrary teachings.

The Federal Circuit stated that when the prior art contains apparently conflicting references, each reference must be weighed for its power to suggest solutions to the skilled artisan. In weighing the suggestive power of each reference, consideration must be given to the degree to which one reference might accurately discredit another.⁵³

In *Young*, the record showed that Knudsen did not test the Carlisle technique under conditions which were directly comparable to the conditions disclosed in Carlisle. Moreover, Knudsen's conclusion that the Carlisle technique was ineffective appeared to directly contradict at least some of the data contained in Knudsen.⁵⁴

The Federal Circuit concluded that, considering the discrepancies between the Knudsen test and the Carlisle disclosure, as well as the tendency of some of Knudsen's data to confirm the Carlisle technique, the Board had correctly determined that Knudsen did not convincingly discredit Carlisle and would not have deterred the skilled artisan from using the teachings of Carlisle. The use of Car-

50. *Id.* at 1091.

51. *Id.*

52. *Id.* at 1092.

53. *Id.* at 1091.

54. *Young*, 18 USPQ2D at 1092.

lisle in the rejection of the claims was therefore not clearly erroneous and the Board's decision affirming the examiner's rejection was therefore affirmed.⁵⁵

C. *Obviousness Rejection Requires Consideration of Whether the Prior Art Discloses That the Skilled Artisan Would Have a Reasonable Expectation of Success in Making the Claimed Invention*

The claimed invention in the case of *In re Vaeck*⁵⁶ was directed to the use of genetic engineering techniques for the production of insecticidal *Bacillus* proteins within transformed cyanobacterial hosts.⁵⁷ The subject matter of the application included a chimeric (i.e., hybrid) gene comprising (1) a gene derived from a bacterium of the *Bacillus* genus whose product is an insecticidal protein, united with (2) a DNA promoter effective for expressing the *Bacillus* gene in a host cyanobacterium, so as to produce the desired insecticidal protein.⁵⁸

The claims had been rejected under 35 U.S.C. § 103. The examiner stated that the primary reference disclosed a chimeric gene capable of being highly expressed in a cyanobacterium, the gene comprising a promoter region effective for expression in a cyanobacterium operably linked to a structural gene encoding the enzyme chloramphenicol acetyl transferase (CAT). The chimeric gene and the transformed host of the primary reference differed from the claimed invention in that, in the primary reference, the structural gene encoded CAT rather than insecticidally active protein.⁵⁹ The secondary references taught genes encoding insecticidally active proteins produced by *Bacillus*, and the advantages of expressing such genes in heterologous hosts to obtain larger quantities of the protein. The examiner contended that it would have been obvious to one of ordinary skill in the art to substitute the *Bacillus*

55. *Id.*

56. 947 F.2d 488, 20 USPQ2D 1438 (Fed. Cir. 1991).

57. *Id.* at 1439.

58. Claim 1 recited:

A chimeric gene capable of being expressed in Cyanobacteria cells comprising: (a) a DNA fragment comprising a promoter region which is effective for expression of a DNA fragment in a Cyanobacterium; and (b) at least one DNA fragment coding for an insecticidally active protein produced by a *Bacillus* strain, or coding for an insecticidally active truncated form of the above protein or coding for a protein having substantial sequence homology to the active protein, the DNA fragments being linked so that the gene is expressed.

Id. at 1440.

59. *Id.* at 1441.

genes taught by the secondary references for the CAT gene in the vectors of the primary reference in order to obtain high level expression of the *Bacillus* genes in the transformed cyanobacteria. The examiner further contended that it would have been obvious to use cyanobacteria as heterologous hosts for expression of the claimed genes due to the ability of cyanobacteria to serve as transformed hosts for the expression of heterologous genes. The examiner's rejection had been affirmed by the Board, and the applicant appealed to the Federal Circuit.⁶⁰

On appeal, the Federal Circuit observed that where a claimed composition has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition; and (2) whether the prior art would also have revealed that in making the claimed composition, those of ordinary skill would have a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be found in the prior art, not in the applicant's disclosure.⁶¹

In *Vaeck*, the Federal Circuit found that there was no suggestion in the primary reference of substituting in the disclosed plasmid a structural gene encoding *Bacillus* insecticidal proteins for the CAT gene utilized for selection purposes. Nor did the Federal Circuit find a suggestion in the secondary references of the substitution of insecticidal *Bacillus* genes for CAT marker genes in cyanobacteria. While the secondary references disclosed expression of *Bacillus* genes encoding insecticidal proteins in certain transformed bacterial hosts, the secondary references did not disclose or suggest expression of such genes in transformed cyanobacterial hosts.⁶²

The similarity between bacteria and cyanobacteria alone was not sufficient to motivate the skilled artisan to substitute cyanobacteria for bacteria as a host for expression of the claimed gene. Evidence of recent uncertainty regarding the biology of cyanobacteria tended to rebut the position that the skilled artisan would have considered the cyanobacteria effectively interchangeable with bacteria as hosts for expression of the claimed gene.⁶³

The Federal Circuit therefore concluded that the prior art of-

60. *Id.* at 1442.

61. *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2D 1529, 1531 (Fed. Cir. 1988).

62. *Vaeck*, 20 USPQ2D at 1443.

63. *Id.*

ferred no explicit or implicit suggestion of the substitution that was the difference between the claimed invention and the prior art. Moreover, the prior art did not convey to those of ordinary skill a reasonable expectation of success in making the claimed composition.⁶⁴ Accordingly, the Federal Circuit reversed the rejection of the claims under 35 U.S.C. § 103.

D. *Obviousness Rejection Can Not Be Overcome by a Terminal Disclaimer*

In *In re Bartfeld*⁶⁵ the claims of a pending application had been rejected under 35 U.S.C. § 103 as obvious in view of two U.S. patent references. One of the two U.S. patent references was owned by the owner of the pending application. Nevertheless, the co-owned patent reference was available as prior art because the co-owned patent reference had an earlier filing date than the pending application and named different inventive entities than the pending application.⁶⁶ The PTO Board affirmed the § 103 rejection.⁶⁷

On appeal to the Federal Circuit, the applicant argued that, in view of the co-ownership of the reference and the pending application, the obviousness rejection under 35 U.S.C. § 103 was comparable to an obviousness-type double patenting rejection. Consequently, the § 103 rejection (like an obviousness-type double patenting rejection) could be overcome by an appropriate terminal disclaimer.⁶⁸

The Federal Circuit noted, however, that there is a basic difference between an obviousness-type double patenting rejection and an obviousness rejection under 35 U.S.C. § 103. An obviousness-type double patenting rejection depends entirely upon subject matter that is *claimed* in an issued U.S. *patent*. An obviousness rejection under 35 U.S.C. § 103 depends upon subject matter that is *disclosed* (regardless of whether the subject matter is claimed) in a prior art *reference* (regardless of whether the reference is an issued U.S. patent). Consequently, a prior art reference that renders claimed subject matter obvious under 35 U.S.C. § 103 does not necessarily create an obviousness-type double patenting situation.⁶⁹

64. See *In re O'Farrell*, 853 F.2d 894, 7 USPQ2D 1673 (Fed. Cir. 1988).

65. 925 F.2d 1450, 17 USPQ2D 1885 (Fed. Cir. 1991).

66. See 35 U.S.C. § 102(e).

67. *Ex Parte Bartfeld*, 16 USPQ2D 1714 (Bd. Pat. App. & Interferences 1990).

68. *Bartfeld*, 17 USPQ2d at 1886. In support of this position, the applicant cited the legislative history underlying the 1984 amendment to 35 U.S.C. § 103 and the Federal Circuit's holding in *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

69. *Bartfeld*, 17 USPQ2D at 1888.

The purpose of a terminal disclaimer is to limit the term of a patent, not to remove a reference as prior art. If claimed subject matter is obvious in view of the prior art, then a terminal disclaimer can not convert that obvious subject matter into unobvious (and therefore patentable) subject matter.⁷⁰ Given these fundamental differences between an obviousness-type double patenting rejection and an obviousness rejection under 35 U.S.C. § 103, the Federal Circuit concluded that a terminal disclaimer is neither an appropriate nor available means for overcoming a rejection under § 103 and affirmed the decision of the Board.⁷¹

E. *Evidence of "Secondary Considerations" May Not Be Sufficient to Defeat a Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 103*

The subject patent in the case of *Ryko Manufacturing Co. v. Nu-Star, Inc.*⁷² was directed to an automatic car wash system electronically activated by an electrical numerical keypad device.

The district court determined that the difference between the claimed invention and the prior art was the claimed invention's substitution of an electrical numerical keypad device for a coin box or other common input device. The district court found that utilization of a numerical keypad device to electronically activate an automatic car wash system was a combination that was clearly suggested by the prior art. The district court determined that the patentee had shown evidence of so-called "secondary considerations" (such as commercial success, long felt but unsolved needs, and the failure of others to invent), but this evidence did not carry sufficient weight to override a determination of obviousness. Accordingly, the district court granted the alleged infringer's motion for summary judgment of patent invalidity under 35 U.S.C. § 103. The patentee then appealed.⁷³

On appeal, the patentee argued that the district court had committed legal error by improperly focusing its obviousness analysis on only one element of the claimed invention (the electrical numerical keypad device), rather than focusing upon the claimed invention as a whole.⁷⁴

70. See *In re Braithwaite*, 54 C.C.P.A. 1589, 379 F.2d 594, 603, 154 USPQ 29, 36 (CCPA 1967).

71. *Bartfield*, 17 USPQ2D at 1889.

72. 950 F.2d 714, 21 USPQ2D 1053 (Fed. Cir. 1991).

73. *Id.* at 1055.

74. *Id.* at 1056.

The Federal Circuit acknowledged that, when analyzing the question of obviousness, the district court must evaluate the claimed invention as a whole and not unduly focus on one facet of the claimed invention.⁷⁵ However, the district court must also determine the principal differences between the claimed invention and the prior art to place the obviousness analysis into proper perspective.⁷⁶ The Federal Circuit concluded that, in evaluating the claimed invention as a whole, the district court in *Ryko* had correctly compared the claimed invention to the prior art and had correctly found only one difference recited in the claims that was not taught by the prior art.⁷⁷

Regarding the "secondary considerations", the Federal Circuit found that the district court had, on the alleged infringer's motion for summary judgment, appropriately accepted the patentee's evidence of commercial success as being true. The alleged infringer had argued that the patentee had failed to produce evidence of the required "nexus" between the commercial success and the merits of the claimed invention. However, the Federal Circuit noted that prima facie evidence of the required nexus is established if there is commercial success and if the invention disclosed in the patent is that which was commercially successful.⁷⁸ In *Ryko* the Federal Circuit found sufficient prima facie evidence in the record to withstand summary judgment on the nexus issue.⁷⁹ Consequently, the district court had appropriately assumed that a nexus existed between the commercial success and the merits of the claimed invention.

However, even though the district court found that the secondary considerations weighed in favor of the patentee, the district court concluded that the secondary consideration did not carry sufficient weight to override a determination of obviousness. The Federal Circuit concluded that, as long as the secondary considerations are contemplated by the district court, it is appropriate for the district court to reach such a conclusion on summary judgment. The holding of the district court was therefore affirmed.⁸⁰

75. *W.L. Gore & Associates v. Garlock, Inc.* 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

76. *Graham v. John Deere*, 383 U.S. 1, 17 (1966).

77. *Ryko*, 21 USPQ2D at 1056.

78. *Demaco Corp. v. F. Von Langsdorff Licensing, Ltd.*, 851 F.2d 1387, 1392, 7 USPQ 2d 1222, 1226 (Fed. Cir.), *cert. denied*, 488 U.S. 956 (1988).

79. *Ryko*, 21 USPQ2D at 1058.

80. *Id.*

F. *Obviousness-type Double Patenting Rejection Does Not Mean That the First-filed Patent is a Prior Art Reference Against the Later-filed Application*

The patentee in the case of *Quad Environmental Technologies Corporation v. Union Sanitary District*⁸¹ was the owner of two patents. The earlier issued '589 patent described and claimed a method of removing odors from wet waste gas streams. The later issued '461 patent described and claimed a method of removing odors from dry waste gas streams. Both patents had been filed within a year of one another, and both patents named the same inventor.⁸²

The patentee had requested, and the PTO had granted, reexamination of the '461 patent. The Reexamination Order stated that the '589 patent raised a new question of patentability under the judicially-created doctrine of obviousness-type double patenting.⁸³

To "obviate" the issue of obviousness-type double patenting, the patentee had filed a terminal disclaimer, disclaiming that portion of the term of the '461 patent which extended beyond the expiration date of the '589 patent. The examiner held that the terminal disclaimer resolved the issue of obviousness-type double patenting, and a Reexamination Certificate was issued.⁸⁴

The patentee had then sued the alleged infringer for infringement of the reexamined '461 patent. The district court had granted the alleged infringer's motion for summary judgment of invalidity for obviousness under 35 U.S.C. § 102(b)/§ 103. The motion had been based on the patentee's pre-trial stipulation that the invention disclosed in the '589 patent had been in commercial use more than one year before the filing of the '461 patent.⁸⁵

The district court had not made an independent finding that the '461 patent claims were obvious in view of the '589 patent disclosure. Instead, the district court held that the patentee's filing of the terminal disclaimer to obviate the double patenting issue was an admission that the '461 patent claims were obvious in view of the '589 patent disclosure. The district court thus held that the patentee was estopped from arguing that the '461 claims were unobvious in view of the process disclosed in the '589 patent.⁸⁶

The patentee appealed the summary judgment of the district

81. 946 F.2d 870, 20 USPQ2D 1392 (Fed. Cir. 1991).

82. *Id.* at 1393.

83. *Id.*

84. *Id.*

85. *Id.*

86. *Quad Environmental Technologies*, 20 USPQ2D at 1394.

court holding all the claims of the '461 patent invalid on the basis of obviousness.⁸⁷

On appeal, the Federal Circuit observed that a rejection for obviousness-type double patenting means that the claims of a later patent application are deemed obvious from the *claims* of an earlier patent.⁸⁸ A rejection for obviousness-type double patenting does not mean that the first-filed patent is a prior art reference under § 102/§ 103 against the later-filed application.⁸⁹ Thus, the "obviation" of an obviousness-type double patenting by filing a terminal disclaimer has no effect on a rejection under § 103 based on the first-filed patent. A rejection under § 103 based on the first-filed patent can not be overcome by a terminal disclaimer.⁹⁰ Thus, a terminal disclaimer is not an admission of obviousness of the later-filed claimed invention in light of the earlier-filed disclosure, for that is not the basis of the disclaimer.

The Federal Circuit therefore concluded that the district court had incorrectly granted summary judgment based on an error of law. The Federal Circuit reversed the grant of summary judgment and remanded for trial.⁹¹

G. *Obviousness-type Double Patenting Rejection of Commonly Owned Applications Claiming Separate and Independent "Subcombination" Inventions Requires A "Two-way" Patentability Determination*

The case of *In re Braat* involved a pending application to Braat and an issued patent to Dil.⁹² Both the Dil patent and the Braat application were assigned to the same assignee. The Dil patent had issued in June 1980 based upon an application filed in January 1979. The pending Braat application had been filed in July 1978.⁹³

Both the Braat application and the Dil patent were directed to compact discs. The Braat application was directed to a technique for controlling the phase depth of information areas on compact discs by varying the physical depth of the information areas. The Dil patent was also concerned with controlling the phase depth of

87. *Id.* at 1392.

88. *In re Longi*, 759 F.2d 887, 893, 225 USPQ 645, 648 (Fed. Cir. 1985); *In re Braithwaite*, 54 C.C.P.A. 1589, 379 F.2d 594, 600, 154 USPQ 29, 34 (CCPA 1967).

89. *In re Bowers*, 53 C.C.P.A. 1590, 359 F.2d 886, 887, 149 USPQ 570, 572 (CCPA 1966).

90. *Bowers*, 359 F.2d at 891 n. 7, 149 USPQ at 575 n. 7.

91. *Quad*, 20 USPQ2D at 1396.

92. *In re Braat*, 937 F.2d 589, 19 USPQ2D 1289 (Fed. Cir. 1991).

93. *Id.* at 1290.

information areas on compact discs, but was primarily concerned with the effect that the angle of the side walls of the information areas had on the phase depth.⁹⁴

The Dil patent expressly acknowledged the Braat invention, and stated that a compact disc having angled side walls (as taught by Dil) was particularly useful when combined with an alternating phase depth structure (as taught by Braat). Claim 1 of the Dil patent was directed to a compact disc having angled side walls. Claims 5 and 6 of the Dil patent, which depended from claim 1, were directed to a compact disc having angled side walls (as taught by Dil) in combination with an alternating phase depth structure (as taught by Braat).

The PTO Board affirmed the rejection of the claims of the Braat application on grounds of obviousness-type double patenting in view of dependent claims 5 and 6 of the Dil patent.⁹⁵

On appeal, the Federal Circuit agreed with the Board that the rejected claims of the Braat application were obvious in view of claims 5 and 6 of the Dil patent. However, the Federal Circuit found that the Board had erred in sustaining the obviousness-type double patenting rejection without making a corresponding determination that claims 5 and 6 of the Dil patent were obvious in view of the rejected claims of the Braat application. In the terminology used by the Federal Circuit, the Board had erred in applying a "one-way" patentability determination instead of a "two-way" determination.⁹⁶

Such a "two-way" patentability determination applies where, for example, an applicant files a first application for a "basic" invention and then subsequently files a second, separate application for an "improvement" invention. As a matter of policy, such an applicant should not be penalized by the different rates of progress of the two applications through the PTO.⁹⁷ Therefore, if the later filed improvement patent issues before the earlier filed basic patent, a double patenting rejection is only proper against the claims of the basic patent if the improvement invention is not patentably distinct

94. *Id.* at 1291.

95. Obviousness-type double patenting is a judicially created doctrine intended to prevent improper extension of the patent term by prohibiting claims in a second patent which define an obvious variation of an invention claimed in a first patent. *In re Longi*, 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed. Cir. 1985); *In re Vogel*, 57 C.C.P.A. 920, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970).

96. *Braat*, 19 USPQ2D at 1292.

97. *Id.* at 1293.

from the basic invention.⁹⁸ In such a situation, the order in which the two applications issue is irrelevant. The relevant determination is whether the improvement invention is patentably distinct from the basic invention.⁹⁹

The Federal Circuit determined that the same policy should apply to the claims of the Braat application, even though the Federal Circuit did not consider the Dil invention to be an "improvement" of the Braat invention. Instead, the Federal Circuit viewed the Dil patent and the Braat application as disclosing separate and independent "subcombination" inventions. Dil had simply combined these two separate subcombination inventions to form a third invention, which third invention was defined in dependent claims 5 and 6 of the Dil patent.¹⁰⁰

The Federal Circuit reasoned that the common assignee of the Dill and Braat applications should not be penalized merely because the Dil patent happened to have issued first. Therefore, a double patenting rejection would be sustainable only if the rejected claims of the *Braat* application were obvious in view of claims 5 and 6 of the Dil patent, and claims 5 and 6 of the Dil patent were obvious in view of the rejected claims of the *Braat* application (thereby establishing the absence of a patentable distinction between claims 5 and 6 of Dil and the rejected claims of *Braat*).¹⁰¹

The Federal Circuit found that claims 5 and 6 of the Dil patent were not obvious in view of the rejected claims of the Braat application. The Federal Circuit therefore concluded that the obviousness-type double patenting rejection was in error, and reversed the decision of the Board.¹⁰²

III. THE PATENT SPECIFICATION - 35 U.S.C. § 112

A. *The Written Description Requirement is Separate and Distinct from the Enablement Requirement*

The patentee in the case of *Vas-Cath Inc. v. Mahurkar* had filed a U.S. design patent application directed to a double lumen catheter.¹⁰³ The patentee had also filed a Canadian design patent application comprising the same drawings as the U.S. design patent application. The Canadian design patent application ultimately is-

98. *In re Borah*, 53 C.C.P.A. 800, 354 F.2d 1009, 148 USPQ 213 (CCPA 1966).

99. *Id.*

100. *Braat*, 19 USPQ2D at 1292.

101. *Id.* at 1293.

102. *Id.* at 1294.

103. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2D 1111 (Fed. Cir. 1991).

sued as a Canadian design patent.¹⁰⁴

More than one year after the issuance of the Canadian design patent, the patentee filed two utility patent applications in the U.S. The U.S. utility patent applications included the same drawings as the U.S. design patent application and claimed the benefit of the filing date of the U.S. design patent application. The U.S. utility patent applications issued as U.S. utility patents.¹⁰⁵

After issuance, the patentee was sued by an alleged infringer seeking a declaratory judgment of patent invalidity and non-infringement. The alleged infringer argued that the U.S. utility patents were not entitled to the filing date of the U.S. design patent application under 35 U.S.C. § 120, because the drawings of the U.S. design patent application did not provide an adequate "written description" of the invention claimed in the U.S. utility patents, as required by 35 U.S.C. § 112, ¶1.¹⁰⁶ The alleged infringer asserted that, as a consequence, the U.S. utility patents were anticipated by the Canadian design patent under 35 U.S.C. § 102(b).¹⁰⁷

The alleged infringer moved for summary judgment on the validity issue. For purposes of the summary judgment motion, the patentee conceded that if the U.S. utility patents were not entitled to the filing date of the U.S. design patent application under 35 U.S.C. § 120, then the Canadian design patent would represent an anticipating § 102(b) reference against the claims of the U.S. utility patents.¹⁰⁸

The district court agreed with the alleged infringer and held the U.S. utility patents invalid under 35 U.S.C. § 102(b).¹⁰⁹ The patentee appealed.

The issue on appeal was whether the district court erred in concluding, on summary judgment, that the disclosure of the U.S. design patent application did not provide a § 112, ¶1 "written description" adequate to support the claims of the U.S. utility patents.¹¹⁰

104. *Id.* at 1112.

105. *Id.* at 1113.

106. The first paragraph of 35 U.S.C. § 112 requires that:

the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

107. *Vas-cath*, 19 USPQ2D at 1116.

108. *Id.* at 1117.

109. *Vas-Cath Inc. v. Mahurkar*, 745 F. Supp. 517, 17 USPQ2D 1353.

110. *Vas-Cath*, 19 USPQ2D at 1117.

The Federal Circuit initially noted that, under proper circumstances, drawings alone may be sufficient to provide the "written description of the invention" required by § 112, ¶1.¹¹¹

The Federal Circuit then explained the extent to which the "written description" requirement of 35 U.S.C. § 112, ¶1, is separate and distinct from the enablement ("make and use") requirement of 35 U.S.C. § 112, ¶1.¹¹² As interpreted by the Federal Circuit, the "written description" requirement requires more than a mere explanation of how to "make and use" the invention.¹¹³ The written description requirement also requires the applicant to convey, with reasonable clarity to those skilled in the art that, as of the filing date, the applicant was in possession of the invention claimed.¹¹⁴

Thus, in *Vas-Cath*, the proper test under the "written description" requirement was whether the drawings of the U.S. design patent application conveyed with reasonable clarity to the skilled artisan that the patentee had in fact invented the catheter recited in the claims of the U.S. utility patents. The proper test was not whether the drawings of the U.S. design patent application necessarily excluded all diameters other than those within the range claimed in the U.S. utility patents, as the district court had erroneously assumed.¹¹⁵

In *Vas-Cath* the patentee had submitted the declaration of an expert explaining why a skilled artisan, studying the drawings of the U.S. design patent application, would have understood from the drawings that the catheter must have a diameter within the range recited by the claims of the U.S. utility patents. The district court had relied upon later patents issued to the patentee which disclosed diameter ratios that differed from those in the U.S. utility patents. However, since application sufficiency under § 112, ¶1, must be

111. *Id.* at 1114.

112. In *In re Wilder*, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 1209, 84 L. Ed. 2d 323, 105 S. Ct. 1173 (1985), the Federal Circuit stated: "The description requirement is found in 35 U.S.C. § 112 and is separate from the enablement requirement of that provision." However, in *Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 1421, 5 USPQ2D 1194, 1197 (Fed. Cir. 1987), *cert. denied*, 486 U.S. 1008, 100 L. Ed. 2d 198, 108 S. Ct. 1735 (1988), the Federal Circuit had stated: "The purpose of the [written] description requirement [of section 112, first paragraph] is to state what is needed to fulfill the enablement criteria. Those requirements may be viewed separately, but they are intertwined. . . . The written description must communicate that which is needed to enable the skilled artisan to make and use the claimed invention."

113. *Vas-Cath*, 19 USPQ2D at 1117.

114. *Id.*

115. *Id.*

judged as of the filing date,¹¹⁶ the Federal Circuit viewed these later patents involving different range limitations as being irrelevant.¹¹⁷

The Federal Circuit held that the patentee's unrefuted declaration evidence gave rise to a genuine issue of material fact inappropriate for summary disposition. The district court's grant of summary judgment holding the U.S. utility patents invalid under 35 U.S.C. § 102(b) was reversed and the case remanded for further proceedings.¹¹⁸

B. *The First Paragraph of § 112 Requires That the Scope of the Claims Must Bear a "Reasonable Correlation" to the Scope of Enablement Provided by the Specification*

The claimed invention in the case of *In re Vaeck*¹¹⁹ was directed to the use of genetic engineering techniques for the production of insecticidal *Bacillus* proteins within transformed cyanobacterial hosts.¹²⁰ The subject matter of the application included a chimeric (i.e., hybrid) gene comprising (1) a gene derived from a bacterium of the *Bacillus* genus whose product is an insecticidal protein, united with (2) a DNA promoter effective for expressing the *Bacillus* gene in a host cyanobacterium, so as to produce the desired insecticidal protein.¹²¹

In addition to describing the claimed invention in generic terms, the patent application disclosed two particular species of *Bacillus* as sources of insecticidal protein and nine genera of cyanobacteria as useful hosts. The relevant working examples described in the application detailed the transformation of a single strain of cyanobacteria.¹²²

The examiner had rejected the claims under 35 U.S.C. § 112,

116. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 USPQ2D 1461, 1464 (Fed. Cir. 1989).

117. *Vas-Cath*, 19 USPQ2D at 1119.

118. *Id.* at 1120.

119. 947 F.2d 488, 20 USPQ2D 1438 (Fed. Cir. 1991).

120. *Id.* at 1439.

121. Claim 1 recited:

A chimeric gene capable of being expressed in Cyanobacteria cells comprising: (a) a DNA fragment comprising a promoter region which is effective for expression of a DNA fragment in a Cyanobacterium; and (b) at least one DNA fragment coding for an insecticidally active protein produced by a *Bacillus* strain, or coding for an insecticidally active truncated form of the above protein or coding for a protein having substantial sequence homology to the active protein, the DNA fragments being linked so that the gene is expressed.

Id. at 1440.

122. *Id.*

first paragraph, on the ground that the disclosure was enabling only for claims limited in accordance with the specification as filed. The examiner took the position that undue experimentation would be required of the skilled artisan to practice the claimed invention, in view of the unpredictability in the art, the breadth of the claims, the limited number of working examples and the limited guidance provided in the specification. The examiner's rejection had been affirmed by the Board, and the applicant appealed to the Federal Circuit.¹²³

On appeal, the Federal Circuit noted that, although the first paragraph of 35 U.S.C. § 112 does not so state, enablement requires that the specification teach the skilled artisan to make and use the invention without "undue experimentation." Some degree of experimentation is permissible. The issue is whether the amount of experimentation required to make and use the invention is "undue."¹²⁴

Moreover, the first paragraph of § 112 requires that the scope of the claims must bear a "reasonable correlation" to the scope of enablement provided by the specification.¹²⁵ The first paragraph of 35 U.S.C. § 112 requires sufficient disclosure, either through illustrative examples or terminology, to teach the skilled artisan how to make and use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the skilled artisan to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility. Where a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than the disclosure of an invention involving a "predictable" factor (such as a mechanical or electrical element).¹²⁶

In *Vaeck*, the Federal Circuit observed that the rejected claims were not limited to any particular genus or species of cyanobacteria. Cyanobacteria are a diverse and relatively poorly studied group of organisms, comprising 150 different genera, and heterologous gene expression in cyanobacteria is "unpredictable." Only one particular species of cyanobacteria was employed in the working examples of the specification, and only nine genera of cyanobacteria were men-

123. *Id.* at 1442.

124. *In re Wands*, 858 F.2d 731, 736-37, 8 USPQ2D 1400, 1404 (Fed. Cir. 1988).

125. *In re Fisher*, 57 C.C.P.A. 1099, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

126. *Id.*

tioned in the entire patent application.¹²⁷

Consequently, there was no reasonable correlation between the narrow disclosure in the application and the broad scope of protection sought in the claims encompassing gene expression in any and all cyanobacteria. Taking into account the relatively incomplete understanding of the biology of cyanobacteria as of the application's filing date, as well as the limited disclosure of particular cyanobacterial genera operative in the claimed invention, the Federal Circuit found that the Board had not erred in rejecting the claims under § 112, first paragraph. Accordingly, the Federal Circuit affirmed the rejection of the claims under 35 U.S.C. § 112, first paragraph.¹²⁸

C. *The First Paragraph of 35 U.S.C. § 112 Requires a Description of All Claim Elements That Are Integral to the Invention and Not Well Known in the Art*

In the case of *In re Buchner*¹²⁹ the claimed invention was directed to a digital transmission system which included a comparator and a divider. Although the specification adequately disclosed the functions performed by the comparator and the divider, the examiner found that neither the comparator nor the divider were standard elements, and that the specification failed to disclose the structure of these two elements. The examiner therefore rejected the application under 35 U.S.C. § 112, ¶1, for failing to describe how to make and use the comparator and the divider without undue experimentation.¹³⁰

In response, the applicant offered a declaration of an expert stating that the divider and the comparator were well-known to the skilled artisan as of the application filing date and that these two elements were "routinely built." The expert's declaration provided details concerning the structure and the function of the comparator and the divider.¹³¹

The Board found that the expert's declaration failed to overcome the § 112 rejection. The Board characterized the declaration as a mere conclusory statement unsupported by any factual documentation showing that the technology concerning the comparator

127. *Vaack*, 20 USPQ2D at 1444.

128. *Id.* at 1445.

129. 929 F.2d 660, 18 USPQ2D 1331 (Fed. Cir. 1991).

130. *Id.*

131. *Id.* at 1332.

and the divider was, in fact, well-known.¹³²

On appeal, the Federal Circuit noted that the elements at issue were integral to the practice of the claimed invention, and that neither the specification nor the prior art appeared to describe the structure of these elements. Consequently, it was reasonable for the examiner in this case to doubt that the claimed invention could have been carried out based upon the specification.

The Federal Circuit further held that if information is not well known in the art, then § 112 requires the specification itself to contain such information. It is not sufficient to provide such information only through an expert's declaration.¹³³ Consequently, even though the expert's declaration in *Buchner* provided significant detail concerning the structure and function of the elements in question, the declaration was insufficient to overcome the rejection under 35 U.S.C. § 112, ¶1.

Moreover, the Federal Circuit found that the expert's declaration was inadequate because the expert's opinion on the ultimate legal issue was a conclusory statement unsupported by any additional evidence.¹³⁴ The declaration failed to provide adequate evidentiary support showing that the divider and the comparator were well known to the skilled artisan as of the filing date and that they were routinely built. Although the declaration described how to construct the divider and the comparator, it did not demonstrate that such construction was well-known to the skilled artisan. The Federal Circuit reasoned that if the comparator and the divider were so well-known and routinely built as of the effective filing date, then the expert should have had no trouble documenting this fact. The declaration did not, however, provide such supporting documentation.¹³⁵

The Federal Circuit therefore concluded that the Board had not erred in affirming the examiner's rejection of the claims for failure to comply with 35 U.S.C. § 112, ¶1, and affirmed the Board's decision.¹³⁶

132. *Id.*

133. *In re Smyth*, 38 C.C.P.A. 1130, 189 F.2d 982, 990, 90 USPQ 106, 112 (1951).

134. *In re Brandstadter*, 484 F.2d 1395, 1405, 179 USPQ 286, 294 (CCPA 1973).

135. *Buchner*, 18 USPQ2D at 1332.

136. *Id.*

D. *For Claims Directed to DNA Sequences, the First Paragraph of 35 U.S.C. § 112 Requires Disclosing How to Make and Use Enough Sequences to Justify the Grant of the Claims*

The subject patent in the case of *Amgen, Inc., v. Chugai Pharmaceutical Co., Ltd.*¹³⁷ was entitled "DNA Sequences Encoding Erythropoietin."¹³⁸ The patent claims were directed to a "purified and isolated DNA sequence" encoding human EPO. Claim 7 encompassed all possible DNA sequences that will encode any polypeptide having an amino acid sequence "sufficiently duplicative" of EPO to possess the property of increasing production of red blood cells.

The district court found that over 3,600 different EPO analogs could be made by substituting only a single amino acid position, and over a million different analogs could be made by substituting three amino acids. Thus, the number of claimed DNA encoding sequences that could produce an EPO-like product was potentially enormous.¹³⁹

The district court concluded that the patent specification was insufficient to enable one of ordinary skill in the art to make and use the invention defined by claim 7 without undue experimentation, and held claim 7 invalid for lack of enablement under 35 U.S.C. § 112.¹⁴⁰ The patentee appealed.

On appeal, the Federal Circuit noted that under 35 U.S.C. § 112, an inventor must provide a disclosure sufficient to enable a skilled artisan to carry out the invention commensurate with the scope of the claims. For claims directed to DNA sequences, 35 U.S.C. § 112 requires disclosing how to make and use enough sequences to justify the grant of the claims sought.¹⁴¹

Claim 7 encompassed every possible analog of a gene containing about 4,000 nucleotides. The patent specification disclosed only how to make EPO and a few analogs. Considering the structural complexity of the EPO gene, the many possibilities for change in its structure, the uncertainty as to what utility might be possessed by these analogs, the Federal Circuit found that the disclosure was

137. 927 F.2d 1200, 18 USPQ2D 1016 (Fed. Cir. 1991).

138. Erythropoietin (EPO) is a protein consisting of 165 amino acids which stimulates the production of red blood cells. *Id.* at 1018.

139. *Id.* at 1027.

140. *Amgen Inc. v. Chugai Pharmaceutical Co.*, 13 USPQ2D 1737 (1990).

141. See *Utter v. Hiraga*, 845 F.2d 993, 998, 6 USPQ2D 1709, 1714 (Fed. Cir. 1988); *In re Robins*, 57 C.C.P.A. 1321, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA 1970).

inadequate in terms of identifying the various analogs that are within the scope of the claim, the methods for making them, and the structural requirements for producing compounds with EPO-like activity.¹⁴²

The record showed that there may be many other genetic sequences that code for EPO-type products. The patent disclosed how to make and use only a few of them. The Federal Circuit therefore concluded that the patent disclosure was inadequate to support a patent claim covering all possible genetic sequences that have EPO-like activity. The Federal Circuit found no error in the district court's conclusion that claim 7 was invalid under 35 U.S.C. § 112.¹⁴³

E. The Particulars of Making a Commercial Embodiment of the Invention Do Not Necessarily Equate With the "Best Mode" of Carrying Out the Invention

The subject patent in the case of *Wahl Instruments, Inc. v. Acvious, Inc.*¹⁴⁴ was directed to a reversible temperature indicating device useful in timing the cooking of eggs. A commercial embodiment of the claimed invention had been mass produced using a technique known as "embedment molding."¹⁴⁵

The inventor had testified that, at the time the patent application had been filed, the best technique for manufacturing the commercial version of the claimed invention had been the embedment molding technique. The alleged infringer asserted that because the patent specification did not describe the embedment molding technique, the patent specification failed to disclose the best mode contemplated by the inventor of carrying out the invention as required by 35 U.S.C. § 112. The district court granted the alleged infringer's motion for summary judgment on this ground, ruling that the claims were invalid for failure to disclose the best mode. The patentee appealed the district court's grant of summary judgment.¹⁴⁶

On appeal, the Federal Circuit observed that a description of a particular manufacturing technique may or may not be required as

142. *Amgen*, 18 USPQ2D at 1027-28.

143. *Id.* at 1028.

144. 950 F.2d 1575, 21 USPQ2D 1123 (Fed. Cir. 1991).

145. The embedment molding technique consists of layering plastic into a mold, followed by an adhesive pouring, onto which a thermochromic layer is placed, followed by a third pouring to complete the device. *Id.* at 1125.

146. *Id.* at 1126.

part of a best mode disclosure respecting a device.¹⁴⁷ There is no mechanical rule that a best mode violation occurs because the inventor failed to disclose a particular manufacturing technique. One must look at the scope of the invention, the skill in the art, the evidence as to the inventor's belief, and all of the circumstances in order to evaluate whether the inventor's failure to disclose a particular manufacturing technique gives rise to an inference that the inventor concealed information which one of ordinary skill in the art would not know.¹⁴⁸

The Federal Circuit further observed that any manufacturing technique requires the selection of specific steps and materials over others. The best mode does not necessarily cover each of these selections. A technique considered "best" in a manufacturing sense may have been selected for a non-"best mode" reason, such as the manufacturing equipment was on hand, certain materials were available, a prior relationship with a supplier was satisfactory, or other reasons having nothing to do with the development of the invention. Thus, the particulars of making a commercial embodiment of the invention do not necessarily equate with the "best mode" of "carrying out" an invention.¹⁴⁹

In *Wahl Instruments* the record indicated that the embedment molding technique had been well known at the time the application had been filed, and that the embedment molding technique would have been utilized if one in the business of fabricating solid plastic articles had been asked to make the claimed invention. There was no proof that the embedment molding technique was "best" for any reason related to the claimed invention, other than the commercial manufacture of a particular embodiment of the invention. The record indicated that the embedment molding technique had been selected as the commercial manufacturing technique solely for reasons of cost and volume.

The Federal Circuit observed that the claimed invention was directed to a device and a method of using the device, not to a method of manufacturing the device. How to mass produce the claimed invention was not part of the claimed invention or a best mode of the claimed invention. The embedment molding technique was therefore not a "mode" of "carrying out" the invention within

147. *Christianson v. Colt Indust. Operating Corp.*, 822 F.2d 1544, 1562, 3 USPQ2d 1254-55 (Fed. Cir. 1987), *vacated on other grounds*, 486 U.S. 800 (1988).

148. *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1531-32, 20 USPQ2d 1300, 1302-03 (Fed. Cir. 1991); *Randomex, Inc. v. Scopus Corp.*, 849 F.2d 585, 587, 7 USPQ2d 1050, 1052 (Fed. Cir. 1988).

149. *Wahl*, 21 USPQ2D at 1127.

the meaning of the statute, and the inventor had concealed nothing respecting the claimed invention by failing to disclose the embedment molding technique.¹⁵⁰

The Federal Circuit concluded that the patent was not invalid for failure to disclose the best mode, and reversed the decision of the district court.¹⁵¹

F. Invalidity for Failure to Disclose the Best Mode Requires Both Knowledge and Concealment of a Better Mode

The case of *Engel Industries, Inc., v. The Lockformer Company*¹⁵² involved an appeal by a patentee from a district court decision holding the patent in suit invalid due to the patentee's failure to disclose the best mode as required by 35 U.S.C. § 112.

On appeal, the Federal Circuit noted that invalidity for failure to set forth the best mode requires that (1) the inventor knew of a better mode of carrying out the claimed invention than the mode disclosed in the specification, and (2) the inventor concealed that better mode.¹⁵³ The element of concealment of the inventor's preferred mode must be established before claims may be invalidated on best mode grounds.¹⁵⁴

The Federal Circuit concluded that the district court had not found such concealment, nor did the evidence support such a finding. Since neither knowledge that there was a better mode nor concealment of that better mode had been established, the Federal Circuit reversed the holding of invalidity for failure to comply with the best mode requirement.¹⁵⁵

150. *Id.*

151. *Id.*

152. 946 F.2d 1528, 20 USPQ2D 1300 (Fed. Cir. 1991).

153. *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927-28, 16 USPQ2D 1033, 1036-37 (Fed. Cir. 1990).

154. *Randomex, Inc. v. Scopus Corp.*, 849 F.2d 585, 588, 7 USPQ2D 1050, 1053 (Fed. Cir. 1988); *In re Gay*, 50 CCPA 725, 309 F.2d 769, 774, 135 USPQ 311, 316 (1962); *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1556-57, 220 USPQ 303, 316 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851, 83 L. Ed. 2d 107, 105 S. Ct. 172 (1984); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384-85, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947, 94 L. Ed. 2d 792, 107 S.Ct. 1606 (1987); *In re Sherwood*, 613 F.2d 809, 816-17, 204 USPQ 537, 544 (CCPA 1980), *cert. denied*, 450 U.S. 994, 210 USPQ 776, 68 L.Ed.2d 193, 101 S.Ct. 1694 (1981); *In re Karnofsky*, 55 CCPA 940, 390 F.2d 994, 997, 156 USPQ 682, 685 (1968).

155. *Engel*, 20 USPQ2D at 1304.

G. *No Cell Deposit May Be Required If the Specification Enables the Skilled Artisan to Prepare the Best Mode Cells from Known Materials*

The subject patent in the case of *Amgen, Inc., v. Chugai Pharmaceutical Co., Ltd.*¹⁵⁶ was entitled "DNA Sequences Encoding Erythropoietin."¹⁵⁷ The patent claims were directed to a "purified and isolated DNA sequence" encoding human EPO.¹⁵⁸

The accused infringer argued that the subject patent was invalid under the best mode requirement of 35 U.S.C. § 112 due to the failure of the patentee to deposit the best mode host cells. The accused infringer contended that the "best mode" requirement for patents involving novel genetically-engineered biological subject matter requires a biological deposit, so that the public has access to exactly the best mode contemplated by the inventor.

The district court disagreed with the accused infringer and held that the patent was valid and had been infringed.¹⁵⁹ The accused infringer appealed.

On appeal, the Federal Circuit noted that analysis of the best mode requirement has two components.¹⁶⁰ The first is a subjective inquiry, asking whether, at the time the patent application was filed, the inventor contemplated a best mode of practicing the claimed invention. If so, then the second inquiry is whether the disclosure is adequate to enable one skilled in the art to practice the contemplated best mode.¹⁶¹

The Federal Circuit then observed that there is a basic distinction between novel genetically-engineered biological materials and biological cells obtained from nature. When a biological sample required for the practice of an invention is obtained from nature, the invention may be incapable of being practiced without access to that specific biological sample. Consequently, the best mode requirement of 35 U.S.C. § 112 requires a deposit of that specific biological sample.¹⁶²

However, when an organism is created by the insertion of genetic material into a cell obtained from generally available sources,

156. 927 F.2d 1200, 18 USPQ2D 1016 (Fed. Cir. 1991).

157. Erythropoietin (EPO) is a protein consisting of 165 amino acids which stimulates the production of red blood cells.

158. *Amgen*, 18 USPQ2D at 1018.

159. *Amgen Inc. v. Chugai Pharmaceutical Co.*, 13 USPQ2D 1737 (1990).

160. *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927, 16 USPQ2D 1033, 1036 (Fed. Cir. 1990).

161. *Amgen*, 18 USPQ2D at 1024.

162. *Id.*

then all that is required by 35 U.S.C. § 112 is a description of the best mode and an adequate description of the means of carrying out the invention. If the cells can be prepared without undue experimentation from known materials, based on the description in the patent specification, then a deposit is not required.¹⁶³

In *Amgen*, the record showed that the invention as it related to the best mode host cells, could be practiced by one skilled in the art following a specific example in the patent specification. The Federal Circuit therefore held that there was no failure to comply with the best mode requirement for lack of a deposit of the cells. The district court finding that the accused infringers had not met their burden of proving a best mode violation was affirmed.¹⁶⁴

H. *Claims Are Properly Declared Invalid Under the Second Paragraph of 35 U.S.C. § 112 If the Meaning of the Claims Is In Doubt*

The subject patent in the case of *Amgen, Inc., v. Chugai Pharmaceutical Co., Ltd.*¹⁶⁵ was entitled "Method for the Purification of Erythropoietin and Erythropoietin Compositions."¹⁶⁶

Claims 4 and 6 of the patent recited a specific activity limitation of "at least about 160,000." The district court found that the term "at least about 160,000" gave no hint as to which specific activity level constituted infringement. The district court therefore held claims 4 and 6 to be invalid for indefiniteness under 35 U.S.C. § 112.¹⁶⁷ The patentee appealed.

On appeal, the Federal Circuit observed that if the meaning of claims is in doubt, then the claims are properly declared invalid under 35 U.S.C. § 112 (especially when there is close prior art).¹⁶⁸

The Federal Circuit found the district court's invalidity holding to be supported by the fact that nothing in the patent specification, prosecution history, or prior art provided any indication as to what range of specific activity was covered by the term "at least about," and by the fact that no expert testified as to a definite meaning for the term "at least about" in the context of the prior art.¹⁶⁹

163. *Id.* at 1025.

164. *Id.*

165. 927 F.2d 1200, 18 USPQ2D 1016 (Fed. Cir. 1991).

166. Erythropoietin (EPO) is a protein consisting of 165 amino acids which stimulates the production of red blood cells. *Id.* at 1018.

167. *Amgen Inc. v. Chugai Pharmaceutical Co.*, 13 USPQ2D 1737 (1990).

168. *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 453, 227 USPQ 293, 297 (Fed. Cir. 1985).

169. *Amgen*, 18 USPQ2D at 1031.

The Federal Circuit cautioned that its holding in *Amgen* that the term "at least about" renders claims 4 and 6 indefinite should not be interpreted as ruling out any and all uses of this term in patent claims. The term "at least about" may be acceptable claim language in appropriate fact situations.¹⁷⁰

I. *The Second Paragraph of 35 U.S.C. § 112 Does Not Require Claims to Recite Each and Every Element Needed for the Practical Utilization of the Claimed Subject Matter*

The subject patent in the case of *Carl Zeiss Stiftung v. Renishaw PLC*¹⁷¹ was directed to a "touch-trigger" probe used in machines for measuring the dimensions of objects to extremely fine precision. Claim 3 of the patent recited a device for performing the function of moving a stylus in a position-determining apparatus so as to provide for repeatable displacement and return of the stylus to a rest position.¹⁷²

In the opinion of the district court, the touch-trigger probe invention disclosed in the patent consisted of more than merely moving a stylus back and forth between a rest position and an unseated position. Focusing on the fact that claim 3 did not recite any electrical circuitry or other signalling means, the district court concluded that claim 3 arbitrarily presented only a part of the invention. The district court held that claim 3 was therefore invalid as lacking claim definiteness under 35 U.S.C. § 112, ¶2. The patentee appealed the judgment of the district court.¹⁷³

On appeal, the Federal Circuit noted that a claim must recite a structure that is capable of performing its purported function.¹⁷⁴ The Federal Circuit found that the device defined by claim 3 was capable of performing the purpose recited in claim 3 of "mounting a stylus in position-determining apparatus" so as to provide for repeatable displacement and return to a rest position.¹⁷⁵

The Federal Circuit further observed that it is not necessary that a claim recite each and every element needed for the practical utilization of the claimed subject matter. A single piece of appa-

170. See, *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed. Cir. 1983).

171. 945 F.2d 1173, 20 USPQ2D 1094 (Fed. Cir. 1991).

172. *Id.* at 1099.

173. *Id.* at 1100.

174. *General Elec. Co. v. United States*, 215 Ct. Cl. 636, 572 F.2d 745, 198 USPQ 65 (1978).

175. *Carl Zeiss*, 20 USPQ2D at 1101.

tus disclosed in the specification as an embodiment of an invention may include several separate subcombination inventions. It is therefore entirely consistent with the claim definiteness requirement of 35 U.S.C. § 112, ¶2 to present "subcombination" claims, drawn to only one aspect or combination of elements of an invention that has utility separate and apart from other aspects of the invention.¹⁷⁶

Consequently, the district court's holding of invalidity based upon a conclusion of lack of claim definiteness was legally incorrect. The Federal Circuit therefore reversed the holding and remanded the case.

J. *The Doctrine of Claim Differentiation Cannot Override the Requirements of the Sixth Paragraph of 35 U.S.C. § 112*

The subject patent in the case of *The Laitram Corporation v. Rexnord, Inc.*¹⁷⁷ was directed to a conveyor belt. Claim 21 of the patent included the following limitation:

means for joining said pluralities [of link ends] to one another so that the axes of said holes of said first plurality are arranged coaxially, the axes of said holes of said second plurality are arranged coaxially and the axes of respective holes of both pluralities of link ends are substantially parallel; . . .¹⁷⁸

Before the district court, the accused infringer argued that the above-quoted means plus function limitation must be interpreted in accordance with 35 U.S.C. § 112, ¶6.¹⁷⁹ Therefore, a proper finding of literal infringement of claim 21 requires that the means in the accused device must be structurally equivalent to the cross member element described in the patent specification which performs the recited function of joining the link ends to one another.¹⁸⁰

The patentee argued that an interpretation which reads the structural limitation of a cross member into claim 21 is impermissi-

176. *Bendix Corp. v. United States*, 600 F.2d 1364, 1369, 220 Ct. Cl. 507, 514, 204 USPQ 617, 621 (1979).

177. 939 F.2d 1533, 19 USPQ2D 1367 (Fed. Cir. 1991).

178. *Id.*

179. 35 U.S.C. § 112, ¶6 provides:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

180. *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1580, 12 USPQ2D 1382, 1386-87 (Fed. Cir. 1989).

ble despite § 112, ¶6, because claim 24 of the patent (a claim which depended from claim 21, but which was not in suit) specifically recited a cross member. The patentee asserted that claim 21 cannot also require a cross member because to do so would violate the doctrine of claim differentiation.¹⁸¹

The district court held that § 112, ¶6 was inapplicable to the above-quoted limitation, because the means plus function language already included a recital of structure. The district court therefore did not compare the accused device to the cross member structure disclosed in the patent specification. Instead, the district court held that the above-quoted claim limitation was literally met by the accused device because the accused device included a means for performing the recited function of joining. The district court therefore ruled that claim 21 was literally infringed by the accused device.¹⁸² The accused infringer appealed the judgment of the district court.

On appeal, the Federal Circuit found that the applicability of § 112, ¶6 was not precluded merely because the means plus function language included a recital of structure.¹⁸³ The Federal Circuit found that the recital of structure in the means plus function language merely served to further specify the function performed by the means. In other words, the recital of structure merely told what the "means-for-joining" did, but did not tell what the "means-for-joining" was structurally. The district court had therefore erred, as a matter of law, by not interpreting the above-quoted subparagraph in accordance with § 112, ¶6.

Regarding the patentee's argument that claim 24 prevented claim 21 from being interpreted as statutorily mandated by 35 U.S.C. § 112, ¶6, the Federal Circuit noted that claim differentiation is a judicially created guide to claim interpretation. This judicially created guide cannot override the express statutory requirements of § 112, ¶6. Therefore, a means-plus-function limitation can not be made open-ended by merely adding a dependent claim which specifically recites the structure disclosed in the specification. Otherwise, the express requirement of § 112, ¶6 could easily be avoided.¹⁸⁴

Moreover, the Federal Circuit found that even under a proper § 112, ¶6 claim interpretation, claims 21 and 24 did not have ex-

181. See, *SRI Int'l v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 1121, 227 USPQ 577, 586-87 (Fed. Cir. 1985) (*en banc*).

182. See, *Laitram Corp. v. Rexnord, Inc.*, 15 USPQ2D 1161 (E.D. Wis. 1990).

183. *Laitram*, 19 USPQ2D at 1367.

184. *Id.*

actly the same scope, and consequently there was no violation of the doctrine of claim differentiation. As properly interpreted under § 112, ¶6, claim 21 literally covered the cross member structure described in the patent specification and equivalents thereof.¹⁸⁵ In contrast, dependent claim 24 literally covered the cross member structure only, and did not literally cover equivalents of the cross member structure. Claim 21 was therefore broader than dependent claim 24.

The Federal Circuit therefore concluded that the district court's finding of infringement had been based upon a legally erroneous claim interpretation, and that under the correct interpretation there was no proof of infringement, either literally or under the doctrine of equivalents. The Federal Circuit therefore reversed the judgment of the district court.¹⁸⁶

K. *Consideration of the Prior Art Is Not Necessary in Applying the Sixth Paragraph of 35 U.S.C. § 112*

The respondents in the case of *Intel Corporation v. U. S. International Trade Commission*¹⁸⁷ had challenged the Commission's finding of infringement of several patent claims containing means-plus-function limitations. The respondents argued that the Commission had improperly construed these means-plus-function limitations in view of the prior art. The respondents asserted that a finding of equivalency of structure under 35 U.S.C. § 112, ¶6, could not be made if the prior art was considered.¹⁸⁸

On appeal, the Federal Circuit pointed out that the respondents had confused equivalent structure under 35 U.S.C. § 112, ¶6 with equivalence under the doctrine of equivalents.

The Federal Circuit noted that to literally meet a means-plus-function limitation, the accused device must (1) perform the identical function claimed for the means element, and (2) perform that function using the same structure as disclosed in the specification or an equivalent structure.¹⁸⁹ In determining equivalent structure under 35 U.S.C. § 112, ¶6, the sole question is whether the single means in the accused device which performs the function stated in

185. *Id.*

186. *Id.*

187. 946 F.2d 821, 20 USPQ2D 1161 (Fed. Cir. 1991).

188. *Id.* at 1179.

189. *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934, 4 USPQ2D 1737, 1739 (1987) (*en banc*); *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 19 USPQ2D 1367, 1369-70 (Fed. Cir. 1991); *Durango Assocs., Inc. v. Reflange, Inc.*, 843 F.2d 1349, 1357, 6 USPQ2D 1290, 1295 (Fed. Cir. 1988).

the claim is the same as, or an equivalent of, the corresponding structure described in the patent specification as performing that function.¹⁹⁰ The aids for determining equivalent structure under 35 U.S.C. § 112, ¶6 are the same as those used in interpreting any other type of claim limitation, namely, the specification, the prosecution history, other claims in the patent, and expert testimony.¹⁹¹

It is therefore not necessary to consider the prior art in determining equivalent structure under 35 U.S.C. § 112, ¶6. The Federal Circuit noted that individual claim limitations, including claim limitations written in means-plus-function terminology, are frequently found in the prior art. However, the fact that the prior art discloses an individual claim limitation does not thereby limit the scope of the claim.¹⁹²

The Federal Circuit therefore affirmed the Commission's findings of infringement.

IV. DIVISIONAL APPLICATIONS - 35 U.S.C. § 121

A. *35 U.S.C. § 121 Will Not Remove a Parent Patent As a Reference if the Principle of "Consonance" Has Been Violated*

The case of *Symbol Technologies, Inc. v. Opticon, Inc.*¹⁹³ involved several patents directed to methods and devices employing lasers to read bar codes.¹⁹⁴

The patentee had filed its original application in February 1980. In the first office action, the examiner had required restriction to one of seven species identified as Groups I - VII. The patentee had elected to prosecute the Group I claims, directed to a light-weight laser scanning apparatus. The original application containing the Group I apparatus claims matured into the "parent" patent.

After the examiner had required restriction, the patentee had filed a divisional application containing method claims drawn to the invention of the non-elected Group VI claims. This divisional application, containing both the Group VI method claims as well as new apparatus claims, had eventually issued as the "divisional" patent.

190. *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1575, 225 USPQ 236, 239 (Fed. Cir. 1985); *Data Line Corp. v. Micro Technologies, Inc.*, 813 F.2d 1196, 1201, 1 USPQ2D 2052, 2055 (Fed. Cir. 1987).

191. *Intel*, 20 USPQ2D at 1179-80.

192. *Id.*

193. 935 F.2d 1569, 19 USPQ2D 1241 (Fed. Cir. 1991).

194. *Id.* at 1243.

After issuance, the patentee had sued for infringement of both the parent patent and the divisional patent. In response, the infringer had argued that the divisional patent was invalid for obviousness-type double patenting over the parent patent. The infringer had asserted that the parent patent was a reference against the divisional patent because the patentee had violated the principle of "consonance" by adding apparatus claims to the divisional patent application.¹⁹⁵

The district court concluded that the divisional patent was not proved invalid for obviousness-type double patenting over the parent patent, and found infringement.¹⁹⁶ The infringer appealed the judgment.

With regard to the issue of double patenting, the Federal Circuit observed on appeal that 35 U.S.C. § 121¹⁹⁷ will not apply to remove a parent patent as a reference where the principle of "consonance" has been violated. The principle of "consonance" requires that the line of demarcation between the independent and distinct inventions that prompted a restriction requirement be maintained throughout prosecution of a divisional application. Therefore, although claims may be amended or added during prosecution of the divisional application, they can not be amended or added so as to bring them back over the line imposed in the original restriction requirement which gave rise to the divisional application. If that line of demarcation is crossed, then the prohibition of the third sentence of § 121 does not apply, and the parent patent may be used as a reference against the invention claimed in the divisional patent.¹⁹⁸

The Federal Circuit read the infringer's assertion to allege that because the Group VI invention had been described as a "method" in the restriction requirement, the addition of apparatus claims in the divisional application had crossed the line of demarcation. However, the record showed that both the method claims and the apparatus claims in the divisional patent were directed to the same

195. *Id.* at 1249.

196. *Symbol Technologies, Inc. v. Opticon, Inc.*, 17 USPQ2d 1737 (S.D.N.Y. 1990).

197. Section 121 provides, in relevant part:

A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

198. *Gerber Garment Technology, Inc. v. Lectra Systems, Inc.*, 916 F.2d 683, 688, 16 USPQ2D 1436, 1440 (Fed. Cir. 1990).

Group VI invention.¹⁹⁹ The Federal Circuit found that the use of the word "method" to describe the Group VI claims during restriction did not mean that the claims were limited to a method, but instead was merely used as a short-hand description of the invented system. Therefore, the line of demarcation established in the restriction requirement had not been crossed, and the parent patent was not available as a reference against the divisional patent under § 121. The Federal Circuit therefore affirmed the judgment of the district court.²⁰⁰

V. INTERFERENCE - 35 U.S.C. § 135

A. *Actual Reduction to Practice May Be Shown by an Adequate Simulation*

The subject invention in the case of *DSL Dynamic Sciences Limited v. Union Switch & Signal, Inc.*²⁰¹ was directed to a coupler mount assembly used to attach equipment to a railway car coupler. The appellant was the assignee of a U.S. patent which had issued in June of 1985, based upon an application filed in September 1983. The appellee was the assignee of a pending U.S. patent application that had been filed in March 1984.²⁰²

An interference had been declared between the appellant's issued patent and the appellee's pending application. During the interference proceeding, the appellee argued that it had reduced the invention to practice in the U.S. in May 1983. In support of its reduction to practice, the appellee presented evidence of tests that had been performed on moving trains during May 1983. These tests involved the use of a prototype of the coupler mount assembly on the caboose of a train.²⁰³

Because the appellant's activity relating to conception and reduction to practice had been performed in Canada, the appellant was prevented by 35 U.S.C. § 104 from establishing an invention date earlier than its U.S. filing date of September 1983. The Board found that the appellee had established a reduction to practice of May 1983, and was therefore entitled to priority of invention.²⁰⁴

The appellant sought review of the Board's decision via an action in federal district court under 35 U.S.C. § 146. In the district

199. *Symbol*, 19 USPQ2D at 1249.

200. *Id.* at 1250.

201. 928 F.2d 1122, 18 USPQ2D 1152 (Fed. Cir. 1991).

202. *Id.* at 1153.

203. *Id.* at 1153-54.

204. *Id.* at 1154.

court, the appellant argued that the appellee's tests had not been performed in the intended environment of the claimed invention and that the tests were therefore insufficient to establish a reduction to practice of the claimed invention. According to the appellant, the purpose of the claimed invention was to obviate the need for a caboose at the end of a train. Therefore, the claimed invention would never be attached to a caboose, but would instead be attached to the coupler of a freight car. If the device tested by the appellee in May 1983 had been attached to a freight car, then the device would have failed. The district court declined to admit the appellant's evidence on this point, and affirmed the award of priority to the appellee.²⁰⁵

On appeal, the Federal Circuit found that even if the appellant's evidence had been admitted by the district court, the appellee would nevertheless still be entitled to the award of priority of invention.²⁰⁶

The Federal Circuit noted that the appellee could meet its burden of proving an actual reduction to practice by showing one of two things: (1) that the use of a coupler mount assembly with a caboose is an intended purpose of the claimed invention; or (2) that if the use of a coupler mount assembly with a caboose is not an intended purpose of the claimed invention, then the tests performed on a caboose coupler sufficiently simulated the conditions present on a freight car coupler to adequately show reduction to practice of the claimed invention.²⁰⁷

The Federal Circuit found that, even if the district court had accepted the appellant's argument that the claimed invention would not be attached to a caboose, the tests performed on a caboose coupler were sufficient to simulate the conditions present on a freight car coupler to adequately show reduction to practice of the claimed invention. Consequently, the appellee was entitled to the award of priority of invention, and the decision of the district court was affirmed.²⁰⁸

205. *Id.*

206. *DSL*, 18 USPQ2D at 1154.

207. *Id.* at 1154-55.

208. *Id.* at 1155.

B. *An Assistant Technician Performing Perfunctory Tasks Under the Supervision of a Senior Scientist Is Not Generally Necessary to Verify the Reliability of Evidence About Scientific Methods or Data*

The subject invention in the case of *Holmwood v. Sugavanam*²⁰⁹ was a chemical fungicide. Both parties had made and marketed the chemical fungicide overseas. An interference had been declared between Holmwood's U.S. patent application and Sugavanam's U.S. patent application.²¹⁰

Sugavanam, the senior party, had an effective filing date of October 16, 1981. To defeat Sugavanam, Holmwood had attempted to show that his invention had been reduced to practice in the U.S. before October 16, 1981.²¹¹

The evidence showed that Holmwood's assignee, a German corporation, had sent the claimed fungicide into the U.S. to verify positive test results previously obtained in Germany. Dr. Walter Zeck, a biological research manager for the U.S. affiliate of Holmwood's assignee, had received the claimed fungicide on or about September 16, 1980.²¹²

Upon receipt of the claimed fungicide, Dr. Zeck began a series of standard tests for effectiveness. Two of Dr. Zeck's laboratory assistants performed the tests in the U.S. and filed reports on the results in October 1980. The test results showed that the claimed fungicide worked for its intended purpose.²¹³

Holmwood presented Dr. Zeck's testimony to the Board. The Board attached negative implications to Holmwood's failure to call Dr. Zeck's laboratory assistants to testify about their ministerial role in the testing. The Board concluded that Dr. Zeck was not "the most satisfactory witness concerning the testing of the samples" and refused to give any weight to Dr. Zeck's testimony in reaching its conclusion.²¹⁴

The Board held that Holmwood had failed to establish a reduction to practice before the effective filing date of Sugavanam. The Board awarded priority to Sugavanam. Holmwood appealed from the decision of the Board.²¹⁵

209. 948 F.2d 1236, 20 USPQ2D 1712 (Fed. Cir. 1991).

210. *Id.* at 1713.

211. *Id.*

212. *Id.*

213. *Id.*

214. *Holmwood*, 20 USPQ2D at 1713.

215. *Id.*

On appeal, the Federal Circuit noted that a junior technician performing perfunctory tasks under the supervision of a senior scientist is not generally necessary to verify the reliability of evidence about scientific methods or data. In the absence of indicia calling into question the trustworthiness of the senior scientist's testimony, the Board may rely on the trained supervisor's testimony to ascertain scientific methods or results.²¹⁶

The Federal Circuit found that, due to Dr. Zeck's careful supervision of the testing program and the indicia of reliability in the test program itself, the Board's refusal to accord full weight to Dr. Zeck's testimony was unreasonable. The Board had erred in determining that, without his assistants' testimony, Dr. Zeck's testimony lacked probative weight.²¹⁷

The Federal Circuit concluded that Dr. Zeck had supplied reliable, un rebutted evidence showing that Holmwood's invention had worked for its intended purpose. If Dr. Zeck's testimony was given proper weight, then a preponderance of the evidence showed that Holmwood's invention had been reduced to practice in the U.S. before Sugavanam's effective filing date. Accordingly, the Federal Circuit reversed the decision of the Board.²¹⁸

C. *A Pending Interference Proceeding May Not Serve as Adequate Reason for the Dismissal of a Declaratory Judgment Action for Non-infringement*

The patent owner in the case of *Minnesota Mining and Manufacturing Co. v. Norton Company*²¹⁹ had filed an application directed to an aluminum-based process for making abrasive material. Several months later, the accused infringer had filed a patent application which claimed both an aluminum-based process for making abrasive material as well as an iron-based process for making abrasive material. The iron-based process was used by the accused infringer in the commercial manufacture of abrasive material.²²⁰

The application directed to the aluminum-based process had issued as a patent while the accused infringer's application was still pending. The accused infringer then initiated an interference proceeding with respect to the aluminum-based process. The patent owner informed the accused infringer (as well as the accused in-

216. *Id.* at 1714.

217. *Id.* at 1715.

218. *Id.*

219. 929 F.2d 670, 18 USPQ2D 1302 (Fed. Cir. 1991).

220. *Id.* at 1303.

fringer's customers) that, under the doctrine of equivalents, the issued patent covered the accused infringer's iron-based process.²²¹

The accused infringer filed suit under 28 U.S.C. § 2201 seeking a declaratory judgment that its iron-based process did not infringe the issued patent.²²² The patent owner moved to dismiss the declaratory judgment litigation, arguing that the results of the interference proceeding might moot any declaratory judgment issued by the district court. The district court granted the patent owner's motion and dismissed the accused infringer's complaint.²²³

On appeal to the Federal Circuit, the accused infringer argued that the harm threatened to its business entitled it to the benefits of 28 U.S.C. § 2201, and that the district court erred in giving too little consideration to the harm which a delay in deciding the infringement litigation would inflict on the accused infringer.²²⁴

The Federal Circuit, agreeing with the accused infringer, noted that the pending interference proceeding would only determine the issue of priority of invention. The pending interference proceeding would not determine the infringement issue underlying the declaratory judgment litigation.²²⁵

If the interference proceeding resulted in an award of priority to the accused infringer, then the infringement litigation would be moot. However, the Federal Circuit found that the mere chance of the infringement litigation becoming moot was not reason enough to dismiss the litigation. The accused infringer was entitled by 28 U.S.C. § 2201 to have a decision on the infringement question and not to have to wait until the final resolution of the interference proceeding.²²⁶

The Federal Circuit noted (without providing specific examples) that there may be situations in which a district court should decline to exercise its discretion to assume jurisdiction under 28 U.S.C. § 2201 when an interference proceeding is underway. However, in the case of *Minnesota Mining and Manufacturing Co.*, the Federal Circuit held that it was an abuse of discretion to have dis-

221. *Id.* at 1304.

222. 28 U.S.C. § 2201, also referred to as the Declaratory Judgment Act, provides:

In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

223. *Minnesota Mining*, 18 USPQ2D at 1304.

224. *Id.* at 1305.

225. *Id.* at 1306.

226. *Id.*

missed a declaratory judgment litigation for non-infringement based on a pending interference proceeding, when the interference proceeding could not decide (or was not likely to moot) the infringement issues raised and when the declaratory judgment plaintiff would likely suffer significant ongoing harm during any delay.²²⁷

The Federal Circuit therefore reversed the judgment of the district court and remanded for further proceedings relating to the declaratory judgment litigation.²²⁸

VI. APPEAL TO THE COURT OF APPEALS FOR THE FEDERAL CIRCUIT - 35 U.S.C. § 141

A. *A District Court Action Under 35 U.S.C. § 146 May Not Preclude an Appeal to the Federal Circuit Under 35 U.S.C. § 141*

The case of *In re Van Geuns*²²⁹ resulted from an interference involving a patent application filed by Van Geuns and a patent issued to Brown. During the interference proceeding, the Board had determined that the subject matter of both Brown's patent and Van Geuns' application was unpatentable for obviousness.²³⁰

Van Geuns appealed the Board's decision to the Federal Circuit under 35 U.S.C. § 141. Brown did not appeal to the Federal Circuit. Instead, Brown's assignee filed suit against Van Geuns' assignee in district court under 35 U.S.C. § 146, alleging that the Board had incorrectly held Brown's patent claims unpatentable. Van Geuns asserted a counterclaim in the district court action.²³¹

Van Geuns moved the Federal Circuit to enjoin Brown's district court proceeding. Brown opposed Van Geuns' motion and moved the Federal Circuit to either remand Van Geuns' appeal to the PTO or to stay Van Geuns' appeal pending resolution of the district court action.²³²

The Federal Circuit found that the patent statute provided both Brown and Van Geuns with the right to seek direct review in separate courts. Section 141 specifically permits a "party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences . . . [to] appeal the decision to the United States Court of Appeals for the Federal Circuit" Section 146

227. *Id.*

228. *Minnesota Mining*, 18 USPQ2D at 1307.

229. 946 F.2d 845, 20 USPQ2D 1291 (Fed. Cir. 1991).

230. *Id.* at 1292.

231. *Id.* at 1295.

232. *Id.*

specifically permits "any party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences . . . [to seek] remedy by civil action" Congress thereby explicitly preserved both alternative routes for review of a Board interference proceeding, and the Federal Circuit concluded that it could not foreclose either route.²³³

The Federal Circuit noted that, to promote efficient judicial management and conservation of scarce judicial resources, it may enjoin parties under its jurisdiction from proceeding with a concurrent action involving the same or related issues.²³⁴ However, in *In re Van Geuns*, the Federal Circuit found that Van Geuns' § 141 appeal did not feature the same parties or issues as Brown's § 146 district court case.²³⁵

Van Geuns' appeal under § 141 contested only the Board's patentability determinations on claims corresponding to the interference count. Van Geuns' appeal was therefore no different than a traditional *ex parte* appeal to the Federal Circuit from a Board determination, and did not include any adverse entity other than the Commissioner.²³⁶

In contrast, Brown's district court litigation under § 146 included Brown's assignee as a party. Moreover, Brown contested the propriety of the Board's rejection of Brown's charges of inequitable conduct against Van Geuns. Van Geuns' § 141 appeal therefore did not feature the same parties or the same issues as Brown's § 146 district court case, and resolution of one case would not dispose of the other litigation.²³⁷

The Federal Circuit therefore denied Van Geuns' motion to enjoin Brown's § 146 district court proceeding, and also denied Brown's motion to either remand Van Geuns' § 141 appeal to the PTO or to stay the appeal pending resolution of the district court action.²³⁸

233. *Id.* at 1294.

234. *Katz v. Lear Siegler, Inc.*, 909 F.2d 1459, 1463, 15 USPQ2D 1554, 1557 (Fed. Cir. 1990).

235. *Van Geuns*, 20 USPQ2D at 1295.

236. *Id.*

237. *Kerotest Mfg. Co. v. C-O-Two Fire Equip. Co.*, 342 U.S. 180, 96 L. Ed. 200, 72 S. Ct. 219 (1952).

238. *Van Geuns*, 20 USPQ2D at 1295.

VII. PROTECTION OF FEDERALLY OWNED INVENTIONS - 35
U.S.C. § 207

A. *A Licensee Under a Patent Owned by the Federal
Government May Maintain an Infringement Action
Without Joining the Federal Government as a Party*

The lawsuit underlying the appeal in *Nutrition 21 v. The United States*²³⁹ was for infringement of a patent owned by the United States.²⁴⁰

The patent licensee had filed suit against an accused infringer and had named the U.S. as a party defendant pursuant to Fed. R. Civ. P. 19(a).²⁴¹ The U.S. had moved to be dismissed from the case, arguing that the suit could be maintained by the licensee alone, without the need for the U.S. as a party. The U.S. based its argument on (1) the enforcement rights granted to the licensee by the U.S. under the patent license agreement, and (2) the authorization provided to federal agencies under 35 U.S.C. 207(a)(2) to grant patent enforcement rights to licensees.²⁴²

239. 930 F.2d 862, 18 USPQ2D 1351 (Fed. Cir. 1991).

240. See, *Nutrition 21 v. Thorne Research, Inc.*, 130 F.R.D. 671, 14 USPQ2D 1244 (W.D. Wash. 1990).

241. Fed. R. Civ. P. 19(a) provides:

Joinder of Persons Needed for Just Adjudication

(a) Persons To Be Joined If Feasible. A person who is subject to service of process and whose joinder will not deprive the court of jurisdiction over the subject matter of the action shall be joined as a party in the action if (1) in the person's absence complete relief cannot be accorded among those already parties or (2) the person claims an interest relating to the subject of the action and is so situated that the disposition of the action in the person's absence may (i) as a practical matter impair or impede the person's ability to protect that interest or (ii) leave any of the persons already parties, subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations by reason of the claimed interest. If the person has not been so joined, the court shall order the person be made a party. If the person should join as a plaintiff but refuses to do so, the person may be made a defendant, or, in a proper case, an involuntary plaintiff. If the joined party objects to venue and joinder of that party would render the venue of the action improper, that party shall be dismissed from the action.

242. Section 207 of Title 35, provides in pertinent part:

(a) Each Federal agency is authorized to —

...

(2) grant nonexclusive, exclusive, or partially exclusive licenses under federally owned patent applications, patents, or other forms of protection obtained, royalty-free or for royalties or other consideration, and on such terms and conditions, including the grant to the licensee of the right of enforcement pursuant to the provisions of chapter 29 of this title as determined appropriate in the public interest;

(3) undertake all other suitable and necessary steps to protect and ad-

The licensee acknowledged that it would not otherwise object to proceeding without the U.S. as a party, but feared that if it proceeded without the U.S., then, after judgment by the district court, the Federal Circuit might subsequently dismiss the infringement action on appeal due to the absence of an indispensable party under Fed. R. Civ. P. 19(b).²⁴³ The licensee therefore opposed the U.S. motion to be dismissed, and moved for realignment of the U.S. as an involuntary plaintiff pursuant to Fed.R.Civ.P. 19(a).

The district court, relying on the case of *Independent Wireless Telegraph Co. v. Radio Corp. of America*,²⁴⁴ concluded that the patent owner is a necessary party to a suit for patent infringement brought by an exclusive licensee. The district court therefore issued an order denying the U.S. motion to be dismissed as a party and realigning the U.S. as an involuntary plaintiff.²⁴⁵

The question on appeal was whether the licensee could maintain a patent infringement action without the U.S. as a party, when the U.S. had authorized the licensee to sue for patent infringement in its own name and on its own behalf.²⁴⁶

In answering this question in the affirmative, the Federal Circuit emphasized the language of the patent license agreement, which expressly empowered the licensee to bring infringement suits in its own name, at its own expense, and on its own behalf, with the U.S. retaining a continuing right to intervene in such suit.²⁴⁷

The Federal Circuit also noted that the public policy concerns

minister rights to federally owned inventions on behalf of the Federal Government either directly or through contract . . .

243. Fed. R. Civ. P. 19(b) provides:

Determination by Court Whenever Joinder not Feasible

If a person as described in subdivision (a)(1)-(2) hereof cannot be made a party, the court shall determine whether in equity and good conscience the action should proceed among the parties before it, or should be dismissed, the absent person being thus regarded as indispensable. The factors to be considered by the court include: first, to what extent a judgment rendered in the person's absence might be prejudicial to the person or those already parties; second, the extent to which, by protective provisions in the judgment, by the shaping of relief, or other measures, the prejudice can be lessened or avoided; third, whether a judgment rendered in the person's absence will be adequate; fourth, whether the plaintiff will have an adequate remedy if the action is dismissed for nonjoinder.

244. 269 U.S. 459, 70 L. Ed. 357, 46 S.Ct. 166 (1926). *Independent Wireless* held that "both the owner and the exclusive licensee are generally necessary parties in the [patent infringement] action in equity." 269 U.S. at 466.

245. *Nutrition 21 v. Thorne Research, Inc.*, 130 F.R.D. at 671, 14 USPQ2d at 1244 (W.D. Wash. 1990).

246. *Nutrition 21*, 18 USPQ2D at 1352.

247. *Id.* at 1354.

underlying passage of the legislation that included 35 U.S.C. 207(a)(2) (specifically, concerns regarding the effective private sector commercialization of inventions resulting from government-financed research) support maintenance of the infringement suit without the U.S. as a party. The case of *Independent Wireless* was not controlling, because that case did not involve a government-owned patent, and because the relevant law had been changed by Congress.²⁴⁸

The Federal Circuit therefore held that, pursuant to 35 U.S.C. 207(a)(2) and the patent license agreement involved, the licensee could maintain an action against the accused infringer without the U.S. as a party. The Federal Circuit expressly declined to consider the question of what preclusive effect the outcome of the lawsuit might have upon the U.S. after its dismissal as a party.²⁴⁹

VIII. REISSUE - 35 U.S.C. § 251

A. *A Patentee Can Not Be Compelled to Seek Reissue Where the Patentee Insists That There Is No Error In the Patent*

In defense to a charge of patent infringement, the alleged infringer in the case of *Green v. The Rich Iron Company, Inc.*²⁵⁰ asserted that the patent was invalid under 35 U.S.C. § 102(b) because the invention had been in public use or on sale more than one year before the application filing date.²⁵¹

The alleged infringer filed a motion for summary judgment on its § 102(b) defense. The district court denied the motion without prejudice. However, the district court *sua sponte* ordered the patentee to seek reissue from the PTO, stating that the PTO was the best forum for consideration of the § 102(b) issue, given the special expertise of the PTO regarding the validity of patents and concerns of judicial economy. The patentee appealed from the district court's order.²⁵²

The issue on appeal was whether a district court can compel a patentee to seek reissue, even though the patentee insists that there is no error in the patent.

The Federal Circuit observed that 35 U.S.C. § 251 permits the PTO to reissue a patent that "is, through error without any decep-

248. *Id.*

249. *Id.* at 1355-56.

250. 944 F.2d 852, 20 USPQ2D 1075 (Fed. Cir. 1991).

251. *Id.*

252. *Id.*

tive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent.”²⁵³ The implementing regulation, 37 C.F.R. § 1.175(a)(1), requires the reissue applicant to file a statement under oath or a declaration “when the applicant verily believes the original patent to be wholly or partly inoperative or invalid, stating such belief and the reasons why.”²⁵⁴ Similarly, 37 C.F.R. § 1.175(a)(5) requires the reissue applicant to explain how the errors arose or occurred, and 37 C.F.R. § 1.175(a)(6) requires the reissue applicant to affirm that the errors occurred without any deceptive intention.²⁵⁵

The Federal Circuit noted that the case authority relied upon by the district court involved reissue applications filed pursuant to the “no-fault” reissue practice, under which an applicant was permitted to file for reissue merely for the purpose of obtaining a PTO determination regarding the effect of newly discovered prior art.²⁵⁶ Such “no-fault” reissue practice is no longer permitted, and reissue is now available only for those patents which, through “error,” are deemed wholly or partly inoperative or invalid.²⁵⁷

The Federal Circuit concluded that if the patentee insists that there is no error in the patent, then ordering the patentee to seek reissue would compel the patentee to attest to error which the patentee does not believe exists. Accordingly, the Federal Circuit reversed the district court order and remanded the case for further proceedings.²⁵⁸

B. *That an Error Could Have Been Discovered at the Time of Prosecution Does Not Preclude Correction of the Error Through Reissue*

The subject patent in the case of *Scripps Clinic & Research Foundation v. Genentech, Inc.*²⁵⁹ was a reissue patent entitled “Ultrapurification of Factor VIII Using Monoclonal Antibodies.” The original patent had contained process claims and product-by-process claims, but had not contained any product claims. The “error” that the inventors had sought to cure via reissue was the claiming of “less than they had a right to claim” in the original patent due to

253. *Id.* at 1076.

254. *Id.*

255. *Green*, 20 USPQ2D at 1076.

256. *See* 37 C.F.R. § 1.175(a)(4) (1981).

257. *Green*, 20 USPQ2D at 1077.

258. *Id.*

259. 927 F.2d 1565, 18 USPQ2D 1001 (Fed. Cir. 1991).

the omission of the product claims.²⁶⁰

Before the district court the accused infringer had argued that the patentee's reason for seeking reissue was inadequate under 35 U.S.C. § 251. The district court granted the accused infringer's motion for partial summary judgment of invalidity on this ground, and the patentee appealed.²⁶¹

On appeal, the Federal Circuit observed that the district court had mistakenly interpreted 35 U.S.C. § 251 as requiring a showing that the error could not have been avoided. However, the reissue statute does not require that no competent attorney could have avoided the error sought to be corrected by reissue. Failure of an attorney to appreciate the full scope of the invention, or failure to claim the invention sufficiently broadly, are among the most common sources of errors in patents. The fact that the error could have been discovered at the time of prosecution does not, by itself, preclude a patentee from correcting the error through reissue.²⁶²

The Federal Circuit found that the inventors had established that they had claimed less than they had a right to claim, that they had done so in error, and that there had been no deceptive intent. The application for reissue therefore fully complied with the requirements of 35 U.S.C. § 251, and the district court's grant of partial summary judgment was reversed.²⁶³

C. *An Objective "Intent to Claim" Is Not Dispositive of Any Required Inquiry Under 35 U.S.C. § 251*

Less than one year after issuance of the subject patent in the case of *In re Amos*,²⁶⁴ the patentees had submitted an application for a broadened reissue. The broadened reissue application sought to add new claims 10-12 to original claims 1-9.²⁶⁵

The PTO Board had found that the disclosure of the original patent failed to set forth an "intent to claim" the subject matter defined by new claims 10-12, and that the "objective intent" of the patentees, as manifested in the original patent, had been to solely claim the invention defined by claims 1-9. Because it found that the failure to claim the subject matter defined by new claims 10-12 was not the result of an "error" as required by 35 U.S.C. § 251, the

260. *Id.* at 1008.

261. *Id.* at 1009.

262. *In re Wilder*, 736 F.2d 1516, 222 USPQ 369 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 1209, 84 L. Ed. 2d 323, 105 S. Ct. 1173 (1985).

263. *Scripps*, 18 USPQ2D at 1009.

264. 953 F.2d 613, 21 USPQ2D 1271 (Fed. Cir. 1991).

265. *Id.* at 1272.

Board affirmed the final rejection of new claims 10-12. The patentee appealed the Board's decision.²⁶⁶

The issue on appeal was whether the concept of "intent to claim" had any role in a rejection of claims submitted during reissue under 35 U.S.C. § 251.²⁶⁷

The Federal Circuit observed that there are four types of error identified in 35 U.S.C. § 251 as being correctable via reissue.²⁶⁸ First, the patentee may correct an error in the specification.²⁶⁹ Second, the patentee may correct a defective drawing. Third, the patentee may correct original claims that are too broad. Fourth, the patentee may correct original claims that are too narrow.²⁷⁰ The basis for correcting original claims that are too broad has generally been the discovery of partially-invalidating prior art.²⁷¹ In contrast, the basis for correcting original claims that are too narrow has been the post-issuance discovery of attorney error in understanding the scope of the invention.²⁷²

The Federal circuit noted that the phrase "intent to claim" does not appear in 35 U.S.C. § 251. The Federal Circuit read the Board's phrase "intent to claim" as a decision that new claims 10-12 were not for the "same invention" as disclosed in the original patent, and interpreted the Board's decision as being based upon a determination that the original patent disclosure did not support the subject matter of new claims 10-12 as required by § 251.²⁷³

The Federal Circuit noted that the inquiry under § 251 as to whether the new claims are for the same invention as disclosed in the original patent is analogous to the analysis required by § 112, ¶1. The entirety of the original patent must be examined and a decision must be made whether, through the "objective eyes" of the hypothetical person having ordinary skill in the art, an inventor could fairly have claimed the new claims in the original application.²⁷⁴

The record showed that the original patent disclosure did cover the subject matter defined by new claims 10-12. Consequently, the

266. *Id.* at 1273.

267. *Id.*

268. *In re Clark*, 522 F.2d 623, 625-26, 187 USPQ 209, 211-12 (CCPA 1975).

269. *In re Salem*, 553 F.2d 676, 679, 193 USPQ 513, 516 (CCPA 1977).

270. *In re Handel*, 312 F.2d 943, 948, 136 USPQ 460, 464 (CCPA 1963).

271. *In re Harita*, 847 F.2d 801, 805, 6 USPQ2d 1930, 1932 (Fed. Cir. 1988).

272. *In re Wilder*, 736 F.2d 1516, 1519, 222 USPQ 369, 371 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 1209 (1985); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1575, 18 USPQ2d 1001, 1009 (Fed. Cir. 1991).

273. *Amos*, 21 USPQ2D at 1274.

274. *Id.* at 1275.

Federal Circuit concluded that the Board had erred in denying the reissue application on the basis of the lack of an "intent to claim." The Federal Circuit therefore reversed the Board, stating that the presence or absence of an objective "intent to claim," standing alone, is not dispositive of any required inquiry under § 251 and cannot, alone, form the basis for a denial of reissue claims.²⁷⁵

D. *Involvement in a Reissue Proceeding May Excuse a Patentee's Delay in Filing Suit for Infringement*

The subject patent in the case of *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*²⁷⁶ had issued in June, 1976. A reissue application was filed in December, 1979, and the reissue proceeding was completed in February, 1985. The patentee did not file suit for infringement until August, 1988. The patentee asserted that its delay in filing suit after it first learned of the infringement was excused due to the patentee's involvement in the reissue proceeding.²⁷⁷

The district court found that the patentee had not shown evidence sufficient to excuse its failure to file suit within six years of the time the patentee knew or should have known of the infringement. The district court therefore concluded that the patentee was barred from maintaining an infringement action by laches.²⁷⁸ The patentee appealed the district court's conclusion.

On appeal, the Federal Circuit noted that if a patentee establishes that it was engaged in "other litigation," then the patentee may avoid the consequences of what would otherwise be an unreasonable delay in filing suit.²⁷⁹ The "other litigation" excuse normally applies when a patentee delays filing suit against an alleged infringer until the conclusion of a prior lawsuit. If the alleged infringer is ultimately sued, and if the alleged infringer had received adequate notice of the alleged infringement, then the time consumed by the other litigation may be considered in determining whether the patentee's delay in filing suit was reasonable.²⁸⁰

For purposes of determining the reasonableness of a patentee's

275. *In re Hounsfield*, 699 F.2d 1320, 216 USPQ 1045 (Fed. Cir. 1983).

276. 944 F.2d 870, 20 USPQ2D 1045 (Fed. Cir. 1991).

277. *Id.* at 1050.

278. Laches may be found when the patentee's delay in filing suit is shown to be unreasonable and unexcused and the alleged infringer has suffered material prejudice or injury as a result of the delay. *Leinoff v. Louis Milona & Sons*, 726 F.2d 734, 741, 220 USPQ 845, 850 (Fed. Cir. 1984).

279. *Watkins v. Northwestern Ohio Tractor Pullers Ass'n*, 630 F.2d 1155, 1162, 208 USPQ 545, 551 (6th Cir. 1980).

280. *Vaupel*, 20 USPQ2D at 1050.

delay in filing suit, the Federal Circuit saw no distinction between litigation raising the issue of patent validity and a PTO proceeding involving patentability. The Federal Circuit therefore reasoned that a reissue proceeding should be treated in the same way as an infringement litigation for purposes determining the applicability of the "other litigation" excuse.²⁸¹

For the "other litigation" excuse to apply, the alleged infringer must be adequately informed of the "other litigation" and must also be adequately informed that the patentee intends to enforce the patent against the alleged infringer after the "other litigation" is completed.²⁸²

In *Vaupel*, the alleged infringer had been actively involved in the reissue proceeding as a protestor. In the opinion of the Federal Circuit, the record left no doubt that the alleged infringer had been adequately informed of the "other litigation", and had been adequately informed of the patentee's intent to enforce the patent after the "other litigation" had been completed. Under these circumstances, the patentee was not required to provide the alleged infringer with written notification of an intent to sue after completion of the reissue proceeding in order to avoid a holding of laches. The district court's conclusion that the alleged infringer had not been adequately informed of the patentee's intent to enforce the patent due to the patentee's failure to provide such written notification to the alleged infringer was legal error.²⁸³

The Federal Circuit concluded that the patentee's delay in filing suit was excused because of the patentee's involvement in the reissue proceeding, and the patentee was not guilty of laches. The judgment of the district court relating to laches was reversed.

IX. PATENT INFRINGEMENT - 35 U.S.C. § 271.

A. *Proper Claim Interpretation Is a Question of Law*

The district court in the case of *Key Manufacturing Group, Inc. v. Microdot, Inc.*²⁸⁴ had found the accused infringer liable for both literal infringement and infringement under the doctrine of equivalents.²⁸⁵ The accused infringer appealed.

281. *Id.* at 1051.

282. *Hottel Corp. v. Seaman Corp.*, 833 F.2d 1570, 1573, 4 USPQ2d 1939, 1940-41 (Fed. Cir. 1987).

283. *Vaupel*, 20 USPQ2d at 1051.

284. 925 F.2d 1444, 17 USPQ2d 1806 (Fed. Cir. 1991). *See also* *Key Mfg. Group, Inc. v. Microdot, Inc.*, 15 USPQ2d 1195 (E.D. Mich. 1990).

285. *Id.* at 1807.

The issue on appeal was one of proper claim interpretation, which is a question of law freely reviewable by the Federal Circuit.²⁸⁶ There were no factual disputes over the meaning of the subject claim language, and neither party asserted that the claim language had anything other than its common, ordinary meaning.²⁸⁷

The Federal Circuit found that the district court's interpretation of the claims conflicted with the straightforward language of the claims, as supported by the patent specification and the prosecution file history. The Federal Circuit concluded that the district court had erred in interpreting the claims, and that the accused product did not literally infringe the properly interpreted claims.²⁸⁸

The Federal Circuit also found that the accused device did not infringe under the doctrine of equivalents, because a hypothetical claim which literally encompassed the accused device would have been obvious in view of the prior art.²⁸⁹

The Federal Circuit therefore reversed the judgment of the district court.

B. Product-by-Process Claims Are Not Limited to the Product Prepared by the Process Set Forth in the Claims

The subject patent in the case of *Scripps Clinic & Research Foundation v. Genentech, Inc.*²⁹⁰ was entitled "Ultrapurification of Factor VIII Using Monoclonal Antibodies." The patent owner had argued that the accused infringer's recombinantly-produced Factor VIII:C product infringed several of the patent's product-by-process claims.²⁹¹ The district court disagreed, concluding that the product-by-process claims could not be infringed unless the accused infringer also practiced the process defined by the claims. The district court therefore refused to grant the patentee's motion for summary judgment of infringement of the product-by-process claims. The

286. *Durango Assocs. Inc. v. Reflange Inc.*, 843 F.2d 1349, 1356, 6 USPQ2D 1290, 1295 (Fed. Cir. 1988); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1270, 229 USPQ 805, 811 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1030, 93 L. Ed. 2d 829, 107 S. Ct. 875 (1987).

287. *Howes v. Medical Components, Inc.*, 814 F.2d 638, 643, 2 USPQ2D 1271, 1273 (Fed. Cir. 1987).

288. *Key Manufacturing*, 17 USPQ2D at 1809.

289. *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 14 USPQ2D 1942 (Fed. Cir. 1990), *cert. denied*, 111 S.Ct. 537, 112 L.Ed.2d 547 (1990).

290. 927 F.2d 1565, 18 USPQ2D 1001 (Fed. Cir. 1991).

291. *Id.* at 1015.

patent owner appealed.²⁹²

On appeal, the Federal Circuit noted that the district court's conclusion conflicted with precedent which indicated that, in determining the patentability of product-by-process claims during prosecution, the product is interpreted as not being limited by the process stated in the claims.²⁹³ The Federal Circuit found that, since claims must be construed the same way for validity and for infringement, the correct reading of product-by-process claims is that they are not limited to the product prepared by the process set forth in the claims. Thus, the Federal Circuit concluded that infringement of the product-by-process claims by the accused infringer's product was an issue which may be considered at trial.²⁹⁴

C. A Claim Element Can Not Be Interpreted Contrary to Its "Plain Meaning" Based Upon an "Alternative" to the Claim Element Described in the Specification

The subject patent in the case of *Unique Concepts, Inc. v. Brown*²⁹⁵ was directed to an "assembly of border pieces" used to attach a fabric wall covering to a wall. The claimed assembly was made up of a number of "right angle corner border pieces" and "linear border pieces" which were arranged to form a frame.²⁹⁶

The alleged infringer had argued that the accused product did not infringe because the accused product did not have corner border pieces which were preformed at a right angle, but instead employed two linear pieces which were each mitered, i.e., cut at a 45 degree angle, and then placed together to form a right angle.²⁹⁷

After trial, the district court entered judgment for the alleged infringer, finding that the mitered linear pieces used by the alleged infringer did not meet the claim language "right angle corner border pieces," either literally or under the doctrine of equivalents.²⁹⁸ The patentee appealed.

On appeal, the Federal Circuit found that the claim language made unambiguous reference to two distinct elements: "linear border pieces" and "right angle corner border pieces." The Federal

292. *Id.*

293. *E.g.*, *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985); *In re Brown*, 59 C.C.P.A. 1036, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972) ; *In re Bridgeford*, 53 C.C.P.A. 1182, 357 F.2d 679, 682 n.5, 149 USPQ 55, 58 n.5 (CCPA 1966).

294. *Scripps*, 18 USPQ2D at 1016.

295. 939 F.2d 1558, 19 USPQ2D 1500 (Fed. Cir. 1991).

296. *Id.* at 1502.

297. *Id.* at 1503.

298. *See*, *Unique Concepts, Inc. v. Brown*, 735 F. Supp. 145 (S.D.N.Y. 1990).

Circuit reasoned that if linear border pieces whose ends are mitered are the same as linear border pieces and a right angle corner piece, then the recitation of both "right angle corner border pieces" and "linear border pieces" in the same claim would be redundant. The Federal Circuit further reasoned that "merging" the two types of claim elements into one would violate the "all elements rule," which requires that to prove infringement, every element in the claim must be found in the accused device either literally or equivalently.²⁹⁹

The Federal Circuit acknowledged that the patent specification contained the following paragraph, which described the option of using "improvised corner pieces" rather than "preformed right-angle corner pieces":

Instead of using preformed right-angle corner pieces of the type previously disclosed, one may improvise corner pieces by miter-cutting the ends of a pair of short linear border pieces at right angles to each other and providing a space between the cut ends to define the necessary storage slot. For this purpose, a temporary spacer may be used to provide exactly the right amount of storage space. The advantage of such corner pieces resides in the fact that linear pieces may be mass-produced at low cost by continuous extrusion, whereas preformed corner pieces must be molded or otherwise fabricated by more expensive techniques. On the other hand, a preformed corner piece is somewhat easier for a do-it-yourselfer to work with.³⁰⁰

The Federal Circuit viewed the above-quoted paragraph as disclosing an "alternative" to the claimed right angle corner border piece, rather than disclosing an example of the claimed right angle corner border piece.³⁰¹ The Federal Circuit stated:

It would run counter to [the requirement of 35 U.S.C. § 112 to particularly point out and distinctly claim the subject matter of the invention] for an applicant for patent to expressly state throughout his specification and in his claims that his invention includes right angle corner border pieces and then be allowed to avoid that claim limitation in a later infringement suit by pointing to one paragraph in his specification stating an alternative

299. See, *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F.2d 878, 889, 8 USPQ2D 1468, 1477 (Fed. Cir. 1988).

300. *Unique Concepts*, 19 USPQ2D at 1503.

301. In a dissenting opinion, Judge Rich viewed the above-quoted paragraph as demonstrating that the specification disclosed two different species of the claimed "right angle corner border pieces": (1) preformed one-piece and (2) mitered, short, linear pieces, arranged at right angles and properly spaced at their junction. *Id.* at 1506.

that lacks that limitation, and thus interpret the claim contrary to its plain meaning. Such a result would encourage an applicant to escape examination of a more broadly-claimed invention by filing narrow claims and then, after grant, asserting a broader scope of the claims based on a statement in the specification of an alternative never presented in the claims for examination.³⁰²

The Federal Circuit concluded that if the patentee had intended to claim mitered linear border pieces as an alternative to right angle corner border pieces, then the patentee was required to persuade the examiner to issue such a claim. The patentee failed to do so. Consequently, the mitered linear border pieces disclosed but not claimed in the patent application were dedicated to the public.³⁰³

The Federal Circuit concluded that the district court had correctly found that a proper construction of the claim language "right angle corner border pieces" required a single preformed corner piece, and that the patent did not literally cover the alleged infringer's corners formed by aligning two mitered straight pieces. The decision of the district court was therefore affirmed.

D. An Infringement Analysis Requires Comparison of the Accused Product to the Patent Claims, Not To Another Product

The subject design patent in the case of *Lund Industries, Incorporated v. Go Industries, Inc.*³⁰⁴ was directed to an automobile sun visor. The parties had previously settled an earlier lawsuit by entering into a settlement agreement in which the accused infringer had conceded the validity of the subject design patent and had admitted infringement.³⁰⁵

After settlement of the earlier lawsuit, the accused infringer had introduced a new sun visor product. The patentee had sought a preliminary injunction, charging that the accused infringer's new sun visor product infringed the design patent.³⁰⁶

In weighing the likelihood of success on infringement, the district court compared the new visor and the admittedly infringing old visor covered by the settlement agreement. The district court

302. *Id.* at 1504.

303. *Edward Miller & Co. v. Bridgeport Brass Co.*, 104 U.S. 350, 352, 26 L. Ed. 783 (1881).

304. 938 F.2d 1273, 19 USPQ2D 1383 (Fed. Cir. 1991).

305. *Id.* at 1384.

306. *Id.* at 1385.

found that the new visor did not colorably differ from the admittedly infringing old visor. Relying on the case of *KSM Fastening Sys. v. H.A. Jones Co.*,³⁰⁷ to justify its comparison of the new visor with the old visor, the district court concluded that the new visor also infringed the design patent and therefore issued a preliminary injunction. The accused infringer appealed.

On appeal, the Federal Circuit found that the district court had erred by relying on *KSM*. In *KSM*, the Federal Circuit had permitted comparison of an infringing device and an accused device as part of the inquiry into whether contempt proceedings were appropriate. However, in *KSM* the Federal Circuit had not permitted comparison of an infringing device and an accused device to determine whether the patent had been infringed.³⁰⁸

In *Lund*, the Federal Circuit held that a proper infringement analysis requires comparison of the accused design to the patent claims, not to another design.³⁰⁹ The district court's departure from this proper infringement analysis was not justified by the accused infringer's prior admission of infringement with respect to a different (albeit related) product. The Federal Circuit therefore vacated and remanded with instructions for the district court to analyze the alleged infringement of the design patent by comparing the accused device to the patent claim.³¹⁰

E. *Application of the Doctrine of Equivalents Is the Exception, Not the Rule*

The subject patent in the case of *Wallace London v. Carson Pirie Scott & Co.*³¹¹ was directed to clamps used to hang clothes securely in travel garment bags. The patentee had alleged that the accused clamps infringed literally and under the doctrine of equivalents. Both the patentee and the alleged infringer had moved for summary judgment relating to infringement. The district court granted the alleged infringer's motion. The patentee appealed only that part of the district court's judgment relating to infringement under the doctrine of equivalents.³¹²

On appeal, the Federal Circuit noted that while designing around patents to make new inventions is encouraged, piracy is not.

307. 776 F.2d 1522, 227 USPQ 676 (Fed. Cir. 1985).

308. *KSM*, 776 F.2d at 1530, 227 USPQ at 682.

309. *KSM*, 776 F.2d at 1530, 227 USPQ at 682; *Amstar Corp. v. Envirotech Corp.*, 823 F.2d 1538, 1545, 3 USPQ2D 1412, 1417 (Fed. Cir. 1987).

310. *Lund*, 19 USPQ2D at 1386.

311. 946 F.2d 1534, 20 USPQ2D 1456 (Fed. Cir. 1991).

312. *Id.* at 1458.

Thus, where an infringer, instead of inventing around a patent by making a substantial change, merely makes an insubstantial change, essentially misappropriating the patented invention, infringement may lie under the doctrine of equivalents. Nevertheless, the Federal Circuit made clear that:

Application of the doctrine of equivalents is the exception, however, not the rule, for if the public comes to believe (or fear) that the language of patent claims can never be relied on, and that the doctrine of equivalents is simply the second prong of every infringement charge, regularly available to extend protection beyond the scope of the claims, then claims will cease to serve their intended purpose. Competitors will never know whether their actions infringe a granted patent.³¹³

In *Wallace London* the Federal Circuit found that the accused device did not work in substantially the same way as the claimed device, and therefore did not infringe under the doctrine of equivalents. Because the evidence showed that the accused device did not meet the claim limitations either literally or equivalently, the alleged infringer was properly entitled to summary judgment as a matter of law. The ruling of the district court was therefore affirmed.³¹⁴

F. Infringement Under the Doctrine of Equivalents Exists Only If the Changes Made to the Claimed Invention By the Accused Infringer Are Not Substantial

The subject patent in the case of *Slimfold Manufacturing Company, Inc. V. Kinkead Industries, Inc.*³¹⁵ had issued in 1974 and was directed to a "Pivot and Guide Rod Assembly for Bi-Fold Door." In 1976, after becoming aware of the patentee's product, the accused infringer instructed its engineers to produce a similar product referred to as the "Type I door." In 1978, after becoming aware of the patent, the accused infringer abandoned the Type I door and began making the "Type II door." The Type II door had been deliberately designed to avoid infringement of the patent.³¹⁶

In a suit for patent infringement, the district court found that the Type I door literally infringed the patent, and that the Type II door infringed under the doctrine of equivalents. The district court also found the infringement to be willful, and held that the patent

313. *Id.* at 1458-59.

314. *Id.* at 1460.

315. 932 F.2d 1453, 18 USPQ2D 1842 (Fed. Cir. 1991).

316. *Id.* at 1845.

owner was entitled to treble damages under 35 U.S.C. § 284 and attorneys fees under 35 U.S.C. § 285.³¹⁷

On appeal, the accused infringer argued that the district court had erred in finding that the Type II door infringed under the doctrine of equivalents and in finding its infringement to be willful.³¹⁸

With respect to infringement under the doctrine of equivalents, the Federal Circuit found that the district court had been overly concerned with the fact that the Type II door had been deliberately designed to avoid infringement. Noting that intentional "designing around" the claims of a patent is not, by itself, a wrong which must be compensated by invocation of the doctrine of equivalents, the Federal circuit stated:

Designing around patents is, in fact, one of the ways in which the patent system works to the advantage of the public in promoting progress in the useful arts, its constitutional purpose. Inherent in our claim-based patent system is also the principle that the protected invention is what the claims say it is, and thus that infringement can be avoided by avoiding the language of the claims.³¹⁹ It is only when the changes are so insubstantial as to result in "a fraud on the patent" that application of the equitable doctrine of equivalents becomes desirable.³²⁰

Therefore, liability for infringement under the doctrine of equivalents may be found only if the changes made to the claimed invention by the accused infringer are not "substantial." Under the *Graver Tank* tripartite test, the changes made to the claimed invention are not "substantial"³²¹ only if the accused device performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claimed invention.

Noting that the claimed invention in *Slimfold* was a mechanical combination in a crowded field and therefore entitled to only a narrow scope of equivalents, the Federal Circuit concluded that the Type II door did not operate in substantially the same way as the claimed invention. Consequently, the Type II door avoided infringement under the doctrine of equivalents, and the district court's finding to the contrary was reversed.³²²

317. *Id.* at 1847.

318. *Id.*

319. *Slimfold*, 18 USPQ2D at 1845-46, quoting *Texas Instruments, Inc. v. U.S.I.T.C.*, 805 F.2d 1558, 1572, 231 USPQ 833, 841-42 (Fed. Cir. 1986).

320. *Slimfold*, 18 USPQ2D at 1846, quoting *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 608, 94 L.Ed. 1097, 70 S.Ct. 854, 85 USPQ 328, 330 (1950).

321. *Slimfold*, 18 USPQ2D at 1846.

322. *Id.*

The Federal Circuit found sufficient evidence in the record to support a finding of willfulness with respect to infringement by the Type I door. However, the Federal Circuit also found that the district court's findings regarding willfulness and the exceptional nature of the case had been influenced by the district court's incorrect assumption that the accused infringer did not avoid infringement when it developed the Type II door. Therefore, the Federal Circuit directed the district court, on remand, to re-determine whether the facts of the case, in light of the holding of no infringement with respect to the Type II door, still merited a finding of willfulness and a finding of "exceptional case" under 35 U.S.C. § 285.³²³

G. *A Patentee Must Prove Substantial Identity As to Each of the Function, Way, and Result Prongs of the Doctrine of Equivalents Test*

The subject patent in the case of *Malta v. Schulmerich Carillons, Inc.*³²⁴ was directed to improvements in the design of handbells, of the type used by music groups in churches, schools, and the like. The subject handbells consisted of a bell, a handle, and a clapper pivotably mounted inside the bell.³²⁵

The patent disclosed two different embodiments for the clapper. The first embodiment had three opposing pairs of "striking surfaces." The second embodiment had three "opposed pairs of buttons" attached to the surface of the clapper. The patent specifically used the term "striking surfaces" with respect to the first embodiment, and used the different term "buttons" with respect to the second embodiment. The patent stated that the two different embodiments shared the same advantages, but varied in design, flexibility and simplicity.³²⁶

Claim 2 of the patent used the broad term "surface portions" to describe the surface of the clapper. Claim 3 of the patent was very similar to claim 2, but used the narrower term "buttons" to describe the surface of the clapper.³²⁷

The patentee had alleged infringement of both claims 2 and 3. The jury had been given special interrogatories asking whether the accused handbells infringed claims 2 and 3 of the patent, either literally or under the doctrine of equivalents. In response, the jury

323. *Id.* at 1847.

324. 952 F.2d 1320, 21 USPQ2D 1161 (Fed. Cir. 1991).

325. *Id.*

326. *Id.* at 1166.

327. *Id.*

had found that claim 2 was not infringed, but that claim 3, while not literally infringed, was infringed under the doctrine of equivalents.³²⁸

The alleged infringer moved for JNOV on the grounds that the evidence was not sufficient to support the finding of infringement under the doctrine of equivalents. The judge agreed, and granted judgment notwithstanding a jury verdict of non-infringement in favor of the alleged infringer.³²⁹ The patentee appealed from the grant of JNOV of non-infringement.³³⁰

On appeal, the Federal Circuit noted that claim 2 of the patent used the broad term "surface portions" to describe the surface of the clapper, whereas claim 3 used the narrower term "buttons." The Federal Circuit reasoned that where a broad term is used in one claim and a narrower term is used in a second claim, and is used with respect to only one embodiment in the specification, the implication is that infringement of the second claim can be avoided by not meeting the narrower term.³³¹

The Federal Circuit further noted that the patent stated that the two different embodiments were alternatives to each other, but varied in design, flexibility and simplicity. The Federal Circuit viewed this as indicating that the two different embodiments did not perform the claimed function in substantially the same "way," as that term is used in the *Graver Tank* test.³³²

In attempting to prove infringement under the doctrine of equivalents, the patentee had principally relied upon the testimony of the inventor. The Federal Circuit found the inventor's testimony to be conclusory and lacking a sufficiently particularized explanation of both how the overall function, way, and result of the accused device are substantially the same as those of the claimed device, and how the plastic/slotted plastic/felt arrangement of the accused device is the equivalent of the claimed "buttons" limitation.³³³ The evidence failed to prove that all three prongs of the *Graver Tank* test had been met, or that the "buttons" limitation had been met equivalently.³³⁴ The Federal Circuit could find no other evidence in the record to provide the necessary substantial evidence on the issue

328. *Malta*, 21 USPQ2D at 1163.

329. *Malta v. Schulmerich Carillons Inc.*, 13 USPQ2d 1900 (E.D. Pa. 1989).

330. *Malta*, 21 USPQ2D at 1164.

331. *Id.* at 1166.

332. *Id.* at 1165.

333. *Id.* at 1166.

334. *Id.*

of infringement under the doctrine of equivalents.³³⁵

The patentee had therefore failed to present evidence sufficient to support a finding of infringement of claim 3 under the doctrine of equivalents, and the Federal Circuit upheld the district court's grant of JNOV on the ground of non-infringement.³³⁶

H. *Prosecution History Estoppel Does Not Necessarily Preclude Application of the Doctrine of Equivalents*

The district court in the case of *Dixie USA, Inc. v. Infab Corporation*³³⁷ had determined that the accused device did not infringe literally, and that infringement under the doctrine of equivalents was precluded by prosecution history estoppel.³³⁸ The district court therefore granted the alleged infringer's motion for summary judgment of non-infringement. The patentee appealed.

On appeal, the patentee argued that, even in the face of prosecution history estoppel, the patentee should still be able to obtain some degree of equivalence, and that a total preclusion of all equivalence should not apply.³³⁹ The Federal Circuit agreed that, as a general proposition, the patentee's argument was correct.³⁴⁰ However, the Federal Circuit found that the district court in *Dixie* had not applied total preclusion.³⁴¹ Instead, the district court had considered the nature of the prior art and the amendments and arguments made during the prosecution of the subject patent application and had concluded that the scope of equivalence being urged by the patentee was precisely that which was forbidden by the prosecution history.³⁴²

The Federal Circuit therefore found that the district court had properly applied the doctrine of prosecution history estoppel and affirmed the decision of the district court.³⁴³

335. *Malta*, 21 USPQ2D at 1166.

336. *Id.* at 1167.

337. 927 F.2d 584, 17 USPQ2D 1968 (Fed. Cir. 1991).

338. *Id.* at 1969.

339. *Id.* at 1970.

340. *Mannesmann Demag Corp. v. Engineered Metal Prod.*, 793 F.2d 1279, 1284, 230 USPQ 45, 48 (Fed. Cir. 1986).

341. *Dixie*, 17 USPQ2D at 1970.

342. *Id.* at 1971.

343. *Id.*

X. DEFENSES TO PATENT INFRINGEMENT - 35 U.S.C. § 282

A. *Intent to Deceive the Patent Examiner Is an Essential Factual Predicate to Inequitable Conduct*

The appeal in the case of *Tol-O-Matic, Inc. v. Proma Produkt - Und Marketing Gesellschaft M.B.H.*³⁴⁴ was taken from the judgment of the district court holding the subject patent unenforceable based on inequitable conduct.³⁴⁵

The inequitable conduct issue involved a reference to Hoffar which the patentee had called to the examiner's attention only after allowance of the claims, following which the examiner had reopened prosecution. There was evidence that the patentee's German patent attorney had known of the Hoffar reference, and had believed that the Hoffar reference was merely cumulative to the prior art already before the U.S. examiner; that the German attorney responded promptly to the request by the U.S. patent attorney for all references cited in other countries; and that after receiving these references, which included the Hoffar reference, the U.S. patent attorney promptly cited the Hoffar reference to the PTO. There was also evidence that the PTO, investigating the charge of inequitable conduct, had found that the Hoffar reference was merely cumulative to other references already of record.³⁴⁶

The jury found that the patentee had made material misrepresentations during patent prosecution, and that the patentee had acted with gross negligence, but that the patentee had not intended to deceive the patent examiner.³⁴⁷ Based on these findings, the district court held the patent invalid for inequitable conduct.³⁴⁸

On appeal, the patentee argued that the district court's ruling was contrary to law, in light of the jury's finding that intent to deceive had not been proven.³⁴⁹

The alleged infringer argued that the jury had simply found that intent to deceive had not been proven by clear and convincing evidence, but that the jury's finding of gross negligence did establish a sufficient threshold level of intent, which the district court then correctly balanced against the jury's finding of materiality to sup-

344. 945 F.2d 1546, 20 USPQ2D 1332 (Fed. Cir. 1991).

345. *Id.* at 1333.

346. *Id.* at 1334.

347. *Id.* at 1335.

348. *Id.* at 1336.

349. *Tol-O-Matic*, 20 USPQ2D at 1336.

port a finding of inequitable conduct.³⁵⁰

The Federal Circuit noted that inequitable conduct carries the consequence of permanent unenforceability of the patent.³⁵¹ Forfeiture is not favored as a remedy for actions not shown to be culpable. Consequently, clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required for a holding of inequitable conduct.³⁵² Gross negligence alone, absent culpable intent, does not provide a sufficient basis for a holding of inequitable conduct.³⁵³

The Federal Circuit noted that the jury's specific finding that intent to deceive had not been established, although gross negligence had been established, was not a trivial distinction.³⁵⁴ Since intent to deceive the patent examiner is an essential factual predicate to inequitable conduct, the finding that intent had not been proven bars a ruling of inequitable conduct.³⁵⁵ The Federal Circuit therefore reversed the judgment of inequitable conduct.

B. The Materiality of a Withheld Reference Requires Consideration of Both Similarities and Differences Between the Prior Art and the Claimed Invention

The district court in the case of *Halliburton Company v. Schlumberger Technology Corporation*³⁵⁶ determined that the patentee had engaged in inequitable conduct by withholding an important prior art reference from the PTO during prosecution.³⁵⁷ The patentee admitted that it had been aware of the withheld reference, but had not considered the reference to be material.³⁵⁸ The district court refused to enforce the patent and awarded the accused infringer attorney fees and expenses.³⁵⁹ The patentee appealed.

On appeal, the Federal Circuit initially noted that a two-step

350. *J.P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc.*, 747 F.2d 1553, 223 USPQ 1089 (Fed. Cir. 1984).

351. *Tol-O-Matic*, 20 USPQ2D at 1337.

352. *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939, 15 USPQ2D 1321, 1327 (Fed. Cir.), *cert. denied*, 111 S. Ct. 296, 112 L. Ed. 2d 250 (1990).

353. *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876, 9 USPQ2D 1384, 1392 (Fed. Cir. 1988) (*en banc*), *cert. denied*, 490 U.S. 1067, 104 L. Ed. 2d 633, 109 S. Ct. 2068 (1989).

354. *Tol-O-Matic*, 20 USPQ2D at 1340.

355. *Id.*

356. 925 F.2d 1435, 17 USPQ2D 1834 (Fed. Cir. 1991).

357. *Id.* at 1836.

358. *Id.* at 1841.

359. *Halliburton Co. v. Schlumberger Technology Corp.*, 722 F. Supp. 324, 12 USPQ2D 1765 (S.D. Tex. 1989).

analysis is required to properly find inequitable conduct.³⁶⁰ First, the trial court must determine whether the withheld reference satisfies a threshold level of materiality and whether the applicant's conduct satisfies a threshold showing of intent to mislead.³⁶¹ Second, the trial court must balance materiality and intent.³⁶² The more material the reference, the less culpable the intent required, and vice versa.³⁶³

Regarding materiality, the Federal Circuit noted that a reference is "material" if there is "substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent."³⁶⁴ However, a patent applicant is not obligated to disclose a material reference if the material reference is merely cumulative, or if the reference is less material than those references already before the examiner.³⁶⁵

In determining whether a withheld reference is merely cumulative, or less material than those references already cited, the Federal Circuit observed that consideration must be given to both similarities and differences between the prior art and the claimed invention, including portions of the withheld reference that teach away from the claimed invention.³⁶⁶

In *Halliburton*, the Federal Circuit concluded that the district court had misunderstood the claimed invention, and had therefore failed to appreciate the significance of the differences between the claimed invention and the withheld reference. These differences distinguished the withheld reference from the claimed invention, and also made the withheld reference less material than the cited references.³⁶⁷

Because the withheld reference was less material than the cited references, the patentee was under no obligation to disclose the

360. *Halliburton*, 17 USPQ2D at 1841.

361. *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415, 5 USPQ2D 1112, 1115 (Fed. Cir. 1987); *J.P. Stevens & Co. v. Lex Tex, Ltd.*, 747 F.2d 1553, 1559-60, 223 USPQ 1089, 1092 (Fed. Cir. 1984), *cert. denied*, 474 U.S. 822, 88 L. Ed. 2d 60, 106 S. Ct. 73 (1985).

362. *Under Sea Indus., Inc. v. Dacor Corp.*, 833 F.2d 1551, 1559, 4 USPQ2D 1772, 1777 (Fed. Cir. 1987).

363. *N.V. Akzo v. E.I. Dupont De Nemours*, 810 F.2d 1148, 1153, 1 USFQ2d 1704, 1708 (Fed. Cir. 1987).

364. 37 C.F.R. § 1.56 (1989).

365. *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 992, 6 USPQ2D 1601, 1609 (Fed. Cir. 1988).

366. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 448-49, 230 USPQ 416, 420 (Fed. Cir. 1986), *cert. denied*, 484 U.S. 823, 98 L. Ed. 2d 47, 108 S. Ct. 85 (1987).

367. *Halliburton*, 17 USPQ2D at 1842.

withheld reference to the PTO.³⁶⁸ Consequently, when the patentee decided to withhold the reference from the PTO, the patentee could not have acted with culpable intent to mislead.³⁶⁹

The Federal Circuit therefore concluded that both the district court's materiality and intent findings were clearly erroneous, and that the patentee had not engaged in inequitable conduct. The judgment of the district court was therefore reversed.³⁷⁰

*C. A Reference That Is Material Only to Withdrawn Claims
Can Not Be the Basis of a Holding of Inequitable
Conduct*

The subject patent in the case of *Scripps Clinic & Research Foundation v. Genentech, Inc.*³⁷¹ was entitled "Ultrapurification of Factor VIII Using Monoclonal Antibodies."³⁷² The accused infringer appealed the district court's grant of summary judgment that the patent owner had not engaged in inequitable conduct during prosecution of the subject patent application.³⁷³

The prosecution history of the patent contained numerous references, including a single paragraph abstract written by a Dr. Meyer, as well as a 27 page paper also written by Dr. Meyer. The Meyer paper, which cited the Meyer abstract, contained a much more detailed disclosure than the Meyer abstract. The Meyer paper had been submitted to the PTO by the patent applicant as part of an information disclosure statement. The Meyer abstract had not been submitted to the PTO by the patent applicant, but had been independently discovered by the Examiner.³⁷⁴

On appeal, the accused infringer charged the patent owner with inequitable conduct resulting from the patent owner's failure to bring the Meyer abstract to the examiner's specific attention.³⁷⁵

The Federal Circuit observed, however, that the Meyer abstract merely summarized the Meyer paper, and was therefore merely cumulative to the Meyer paper. A reference that is merely cumulative to other references does not meet the threshold of mate-

368. *Specialty Composites*, 845 F.2d at 992, 6 USPQ2d at 1609; *J.P. Stevens*, 747 F.2d at 1559-60, 223 USPQ at 1092.

369. *Halliburton*, 17 USPQ2D at 1842.

370. *Id.*

371. 927 F.2d 1565, 18 USPQ2D 1001 (Fed. Cir. 1991).

372. *Id.* at 1003.

373. *Id.* at 1004.

374. *Id.* at 1015.

375. *Id.*

riality that is a predicate to a holding of inequitable conduct.³⁷⁶

The Federal Circuit further stated that when a reference is before the examiner, whether through the examiner's search or the applicant's disclosure, it can not be deemed to have been withheld from the examiner. Thus, what is controlling is whether the Meyer abstract had been considered by the examiner, not how the Meyer abstract came to the examiner's attention.³⁷⁷

The accused infringer also charged the patent owner with inequitable conduct because the patent owner had originally sought claims to certain monoclonal antibodies, and had subsequently canceled those claims after the examiner had required the patent owner to provide comparative data with the monoclonal antibodies described in the Meyer abstract.³⁷⁸

The Federal Circuit noted, however, that an applicant has the absolute right to decline to do work suggested by the PTO, and to withdraw claims that had been presented for examination, without incurring liability for inequitable conduct. The Federal Circuit held that a reference that is material only to withdrawn claims can not be the basis of a holding of inequitable conduct.³⁷⁹

The Federal Circuit concluded that, drawing all factual inferences in its favor, the accused infringer had failed to offer evidence or legal argument showing that inequitable conduct could be proven at trial, as to either materiality of the Meyer abstract, or the patentee's intent to deceive or mislead.³⁸⁰ The Federal Circuit therefore affirmed the district court's grant of partial summary judgment of no inequitable conduct based on the Meyer abstract.³⁸¹

D. Disputed Fact Questions Regarding Inequitable Conduct Are Not Appropriately Resolved by Summary Judgment

The subject patent in the case of *Scripps Clinic & Research Foundation v. Genentech, Inc.*³⁸² was a reissue patent entitled "Ultrapurification of Factor VIII Using Monoclonal Antibodies."³⁸³

376. *Halliburton Co. v. Schlumberger Technology Corp.*, 925 F.2d 1435, 1440, 17 USPQ 2d 1834 (Fed. Cir. Feb. 15, 1991).

377. *Scripps*, 18 USPQ2D at 1015.

378. *Id.*

379. *Kimberly-Clark Corp. v. Johnson & Johnson Co.*, 745 F.2d 1437, 1457, 223 USPQ 603, 616-17 (Fed. Cir. 1984).

380. *Scripps*, 18 USPQ2D at 1015.

381. *Id.* at 1016.

382. 927 F.2d 1565, 18 USPQ2D 1001 (Fed. Cir. 1991).

383. *Id.* at 1003.

During the prosecution of the reissue application, the examiner had raised various questions under 35 U.S.C. § 112 relating to the purity of the Factor VIII that was the subject of the proposed product claims. In response, the inventors had made several statements in the record regarding the purity of the claimed Factor VIII.³⁸⁴

The district court had found that the inventors' statements about the purity of the product were unsupported by the evidence. The district court therefore granted partial summary judgment of unenforceability of the claims due to inequitable conduct.³⁸⁵

On appeal, the Federal Circuit noted that there are two essential factual predicates to a determination of inequitable conduct: the materiality of the representation, and whether the representation was made with intent to deceive or mislead.³⁸⁶

In *Scripps* the Federal Circuit found that there was a factual dispute regarding whether the inventors' statements concerning purity were in error. Moreover, there was a factual dispute regarding the inventor's intent to mislead or deceive the examiner, an issue about which the district court had failed to make any finding.³⁸⁷ It was not appropriate to resolve either of these factually disputed issues on summary judgment. The Federal Circuit therefore reversed the grant of partial summary judgment of unenforceability of the claims for inequitable conduct.

E. Determination of Privity Under the Doctrine of Assignor Estoppel Requires Consideration of Both Direct and Indirect Contacts With the Patentee

Assignor estoppel is an equitable doctrine that prevents a patentee who has assigned the rights to a patent from later contending that what was assigned is a nullity.³⁸⁸ The doctrine also bars a similar challenge by any party in privity with the assignor. Privity depends upon the closeness of the relationship based upon a balancing of the equities.³⁸⁹

The complainant in the case of *Intel Corporation v. U. S. Inter-*

384. *Id.* at 1011.

385. *Id.* at 1012.

386. *Modine Mfg. Co. v. Allen Group, Inc.*, 917 F.2d 538, 541, 16 USPQ2D 1622, 1624 (Fed. Cir. 1990).

387. *Scripps*, 18 USPQ2D at 1006.

388. *Diamond Scientific Co. v. Ambico, Inc.*, 848 F.2d 1220, 1224, 6 USPQ2D 2028, 2030 (Fed. Cir. 1988).

389. *Shamrock Technologies, Inc. v. Medical Sterilization, Inc.*, 903 F.2d 789, 14 USPQ2D 1728 (Fed. Cir. 1990).

*national Trade Commission*³⁹⁰ had argued that assignor estoppel prevented a first respondent from challenging the validity of the subject patent because the inventor, a major shareholder and chief executive officer of the first respondent, had assigned the patent to the complainant.³⁹¹ The complainant further argued that assignor estoppel similarly prevented a second respondent from challenging the validity of the subject patent because of the close relationship that the inventor and the first respondent had with the second respondent.³⁹²

The Commission determined that the first respondent was in privity with the inventor, and was therefore prevented by assignor estoppel from challenging the patent's validity. However, the Commission determined that the second respondent did not have sufficient contacts with the inventor to be in privity, and that the second respondent was therefore not estopped from challenging the patent's validity.³⁹³ The complainant appealed the Commission's decision that the second respondent was not in privity with the inventor.

On appeal, the Federal Circuit found that the Commission had improperly limited its analysis to whether the relationship between the inventor and the second respondent was enough to find that the two were in privity.³⁹⁴ In determining whether the second respondent was in privity with the inventor, the Commission should have considered all contacts between the second respondent and the inventor, direct and indirect, including the contacts between the first respondent and the second respondent. The Commission had not adequately considered the part the inventor had played in creating the joint venture between the second respondent and the first respondent, under which both respondents sought to mutually develop the allegedly infringing product.³⁹⁵ The Federal Circuit concluded that the balance of the equities required a finding of privity between the second respondent and the inventor.³⁹⁶

Because of its privity with the inventor and the first respondent, the Federal Circuit concluded that the second respondent should not have been allowed to challenge the validity of the patent. Because the second respondent had been improperly permitted to

390. 946 F.2d 821, 20 USPQ2D 1161 (Fed. Cir. 1991).

391. *Id.* at 1175.

392. *Id.*

393. *Id.* at 1176.

394. *Intel*, 20 USPQ2D at 1177.

395. *Id.*

396. *Id.*

contest the validity of the patent, the Federal Circuit vacated the Commission's holding that claim 1 of the patent was invalid.³⁹⁷

XI. INJUNCTIVE RELIEF - 35 U.S.C. § 283

A. *The Patentee Has the Burden of Showing Likelihood of Success With Respect to Validity and Infringement At the Preliminary Injunction Stage*

The trial court in the case of *Nutrition 21 v. The United States*³⁹⁸ had granted a preliminary injunction pursuant to 35 U.S.C. § 283, which enjoined the alleged infringer from selling or offering for sale a product encompassed within the patent claims.³⁹⁹ On appeal to the Federal Circuit, the alleged infringer sought relief from the injunction on grounds that the district court had erred by failing to set forth adequate findings of fact to support the preliminary injunction.⁴⁰⁰

The Federal Circuit initially noted that the issuance of a preliminary injunction turns upon four factors: 1) the probability that the party seeking the injunction will succeed on the merits; 2) the threat of irreparable harm to the party seeking the injunction should a preliminary injunction be denied; 3) the balance between this harm and the harm that granting the injunction will cause to the other parties; and 4) the public interest.⁴⁰¹

Regarding the first factor (the probability that the party seeking the injunction will succeed on the merits), the Federal Circuit observed that while a patent is presumed valid, that presumption of validity is a *procedural* device that places the burden of going forward and the ultimate burden of persuasion *at trial* on the party attacking the validity of a patent.⁴⁰² Prior to trial, at the preliminary injunction stage, the burden of showing likelihood of success on the merits with respect to the patent's validity, enforceability, and infringement is placed upon the patentee.⁴⁰³ A patentee must therefore "clearly show" that the patent is valid and infringed

397. *Id.* at 1181.

398. 930 F.2d 867, 18 USPQ2D 1347 (Fed. Cir. 1991).

399. *Nutrition 21 v. Thorne Research Inc.*, 130 F.R.D. 671, 14 USPQ2D 1244 (1990).

400. *Id.* at 1245.

401. *Pretty Punch Shoppettes v. Hauk*, 844 F.2d 782, 783, 6 USPQ2D 1563, 1564 (Fed. Cir. 1988).

402. *See* 35 U.S.C. § 282 (1988); *Roger Corp. v. Litton Systems, Inc.*, 757 F.2d 1266, 1270, 225 USPQ 345, 347 (Fed. Cir. 1985).

403. *Atlas Powder Co. v. Ireco Chemicals*, 773 F.2d 1230, 1233, 227 USPQ 289, 292 (Fed. Cir. 1985).

before a court may preliminarily enjoin an alleged infringer.⁴⁰⁴ In the case of *Nutrition 21*, the Federal Circuit found that the required "clear showing" of validity and infringement was absent.⁴⁰⁵

Regarding the second factor (the threat of irreparable harm to the party seeking the injunction), the Federal Circuit noted that without a clear showing of validity and infringement, a presumption of irreparable harm does not arise in a preliminary injunction proceeding.⁴⁰⁶ There is no presumption that money damages will be inadequate. Nor is irreparable harm proven by evidence of the difficulty of calculating losses in market share or speculation that such losses might occur.

The Federal Circuit therefore vacated the preliminary injunction due to the district court's failure to set forth adequate findings of fact to support the preliminary injunction.⁴⁰⁷

B. Preliminary Injunctive Relief Against Infringement Under The Doctrine of Equivalents Requires a Finding That the Function/Way/Result Test Has Been Met

The patentee in the case of *The Conair Group, Inc. v. Automatik Apparate-Maschinenbau Gmbh*⁴⁰⁸ had filed suit against the alleged infringer and had moved for a preliminary injunction. The district court concluded that both literal infringement and infringement under the doctrine of equivalents were reasonably likely to be found, and granted the motion.⁴⁰⁹ The alleged infringer appealed the preliminary injunction order.

The issue on appeal was whether the District Court had abused its discretion, committed an error of law, or seriously misjudged the evidence by granting the patentee's motion for a preliminary injunction.⁴¹⁰

With regard to literal infringement, the Federal Circuit noted that the record contained uncontradicted evidence indicating that at least one limitation of the patent claim was not met by the accused

404. *Roper*, 757 F.2d at 1271-72, 225 USPQ at 348-49; *Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1580-81, 219 USPQ 686, 692 (Fed. Cir. 1983).

405. *Nutrition 21*, 18 USPQ2D at 1347.

406. *Datascope Corp. v. Kontron, Inc.*, 786 F.2d 398, 400, 229 USPQ 41, 42-43 (Fed. Cir. 1986); *Roper*, 757 F.2d at 1271, 225 USPQ at 349.

407. *Roper*, 225 USPQ at 349.

408. 944 F.2d 862, 20 USPQ2D 1067 (Fed. Cir. 1991).

409. *See Conair Group, Inc. v. Automatik Apparate-Maschinenbau*, 19 USPQ2D 1535 (W.D. Pa. 1990).

410. *Conair Group*, 20 USPQ2D at 1069.

device.⁴¹¹ The Federal Circuit therefore concluded that the district court had seriously misjudged the evidence, and that the district court's determination of a likelihood of success on grounds of literal infringement was erroneous.⁴¹²

With regard to infringement under the doctrine of equivalents, the Federal Circuit noted that Rule 52(a) of the Federal Rules of Civil Procedure requires a district court to make findings of fact to support the granting of a preliminary injunction. Failure to provide adequate findings of fact is an error of law.⁴¹³

The Federal Circuit noted that the district court had failed to make any findings that the accused device performed substantially the same function as the claimed invention, that the accused device did so in substantially the same way, or that the accused device obtained the same result.⁴¹⁴ The district court had further failed to make any findings that the range of equivalents sought by the patentee did not "ensnare the prior art."⁴¹⁵ Lastly, the district court had failed to make any findings regarding whether the doctrine of prosecution history estoppel applied to limit the range of equivalents.⁴¹⁶

Since the district court had made none of the required findings with regard to infringement under the doctrine of equivalents, the Federal Circuit found no basis for concluding that there was a likelihood of success on that ground. Consequently, the injunction was vacated.⁴¹⁷

411. *Id.* at 1070.

412. *Id.* at 1071.

413. *Nutrition 21 v. United States*, 930 F.2d 867, 869, 18 USPQ2D 1347, 1349 (Fed. Cir. 1991). Fed. R. Civ. P. 52(a) provides, in pertinent part, that:

In all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon, and judgment shall be entered pursuant to Rule 58; and in granting or refusing interlocutory injunctions the court shall similarly set forth the findings of fact and conclusions of law which constitute the grounds of its action . . .

414. *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. 605, 94 L. Ed. 1097, 70 S. Ct. 854, 85 USPQ 328 (1950).

415. *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 685, 14 USPQ2D 1942, 1949 (Fed. Cir.), *cert. denied*, 111 S. Ct. 537, 112 L. Ed. 2d 547, 59 U.S.L.W. 3392 (1990).

416. *Conair*, 20 USPQ2D at 1070.

417. *Id.*

C. *Preliminarily Injunctive Relief Against Infringement Under the Doctrine of Equivalents Requires Consideration of Whether the Teachings of the Prior Art Would Have Made Obvious the Range of Equivalents Being Asserted*

The patent owner in the case of *We Care, Inc. v. Ultra-Mark International Corp.*⁴¹⁸ had filed suit against the alleged infringer and had sought a preliminary injunction pursuant to 35 U.S.C. § 283 to prevent the manufacture and sale of the accused device while the suit was pending.⁴¹⁹ The district court determined that the patent owner would probably not be able to prove literal infringement, but granted the injunction based on the finding that the patent owner was likely to prove infringement at trial under the doctrine of equivalents.⁴²⁰ The alleged infringer appealed the district court's grant of a preliminary injunction.

On appeal, the Federal Circuit observed that the doctrine of equivalents may not be used to extend a patent owner's right to exclude beyond what could lawfully have been obtained in the original patent application. Therefore, in determining infringement under the doctrine of equivalents, the prior art must be examined to assure that the range of equivalents being asserted does not encroach upon subject matter in the prior art.⁴²¹ This examination necessarily involves consideration of not only what the prior art would have anticipated under 35 U.S.C. § 102, but also what the prior art would have made obvious under 35 U.S.C. § 103, at the time the patent application was filed.

With respect to the requisite prior art analysis, the district court in the case of *We Care* had observed that the none of the relevant prior art references "identically disclosed" every element of the patent claims, as "extended" by the doctrine of equivalents. The Federal Circuit found that the district court's prior art analysis did not go far enough, since the district court failed to consider whether the teachings of the prior art would have made obvious the range of equivalents being asserted for the patent claims.⁴²² The Federal Circuit concluded that the district court had erred by not considering, in an obviousness context, whether a range of equivalents broad

418. 930 F.2d 1567, 18 USPQ2D 1562 (Fed. Cir. 1991).

419. *Id.* at 1563.

420. *We Care, Inc. v. Ultra-Mark Int'l Corp., et al.*, 741 F. Supp. 743, 14 USPQ2D 1804 (D. Minn. 1989).

421. *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 685, 14 USPQ2D 1942, 1949 (Fed. Cir. 1990).

422. *We-Care, Inc.*, 18 USPQ2D at 1565.

enough to find infringement was permissible.⁴²³

Accordingly, the Federal Circuit vacated the preliminary injunction and remanded the case to the district court to determine whether the range of equivalents sought by the patent owner encroached upon the prior art.⁴²⁴

D. Preliminary Injunctive Relief Against Design Patent Infringement Requires a Finding That the Novelty in the Patented Design Has Been Appropriated and That the Ordinary Observer Would Be Deceived

In the case of *Oakley, Inc. v. International Tropic-Cal, Inc.*⁴²⁵ the District Court had granted a preliminary injunction enjoining the alleged infringer from infringing a design patent. The alleged infringer appealed the injunction.⁴²⁶

On appeal, the Federal Circuit noted that under Rule 52(a) of the Federal Rules of Civil Procedure, a preliminary injunction must be supported by findings of facts.⁴²⁷ The test of the adequacy of the findings is whether they are sufficiently comprehensive and pertinent to the issue to form a basis for the decision.⁴²⁸

In the case of a design patent, proof of infringement requires a showing that an ordinary observer would be deceived in a manner that would induce the observer to purchase the accused device supposing it to be the patented design.⁴²⁹ In addition to overall similarity of design, the accused device must also appropriate the novelty in the patented design which distinguishes it from the prior art.⁴³⁰

In *Oakley*, the Federal Circuit found that the district court had failed to make any explicit findings regarding these facts.⁴³¹ The district court had made no express or implied finding that the patent owner was likely to be able to prove at trial that the alleged infringer's products infringed the patent.⁴³² Because the district court's findings of fact were insufficient for proper review of the

423. *Id.*

424. *Id.*

425. 923 F.2d 167, 17 USPQ2D 1401 (Fed. Cir. 1991).

426. *Id.* at 1402.

427. *Id.* at 1403.

428. *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 873, 228 USPQ 90, 98 (Fed. Cir. 1985).

429. *Gorham Mfg. Co. v. White*, 81 U.S.(14 Wall.) 511, , 20 L. Ed. 731 (1872).

430. *Avia Group Int'l, Inc. v. L.A. Gear Cal.*, 853 F.2d 1557, 1565, 7 USPQ2D 1548, 1554 (Fed. Cir. 1988); *Shelcore, Inc. v. Durham Indus., Inc.*, 745 F.2d 621, 628, 223 USPQ 584, 590 (Fed. Cir. 1984).

431. *Oakley*, 17 USPQ2D at 1403.

432. *Id.*

issues, the Federal Circuit vacated the District Court's preliminary injunction and remanded the case for further proceedings.⁴³³

E. Likelihood of Success On the Merits Includes a Showing That the Plaintiff Holds Title to the Patent

The inventor of the patented subject matter in the case of *Filmtec Corporation v. Allied-Signal Inc.*⁴³⁴ had been one of the founders of the plaintiff corporation.⁴³⁵ Prior to founding the plaintiff corporation, the inventor had been employed at a non-profit research organization.⁴³⁶

The inventor's work at the non-profit research organization had been carried out under a contract with the U.S. Government. The contract required the non-profit research organization to grant to the U.S. Government the entire right in any invention made under the contract or any subcontract thereunder. The contract further required the non-profit research organization to warrant that it would obligate its employees to assign their rights in any invention made under the contract to the non-profit research organization.⁴³⁷

The inventor had left the non-profit research organization in January of 1978. The subject patent application had been filed by the inventor in February of 1979. The inventor assigned his rights in the patent application to the plaintiff corporation. After the subject patent issued, the plaintiff corporation sued the alleged infringer for infringement.⁴³⁸

The alleged infringer asserted that the invention claimed in the patent had been made by the inventor while employed by the non-profit research organization. The alleged infringer asserted that, under the contract between the non-profit research organization and the Government, the Government held legal title to the invention and therefore the inventor had no rights to assign to the plaintiff. Since the plaintiff lacked legal title to the patent, the plaintiff had no standing to bring an infringement action under the patent.⁴³⁹

The district court concluded that, as a matter of law, even if the invention had been made while the inventor had been employed

433. *Id.* at 1404.

434. 939 F.2d 1568, 19 USPQ2D 1508 (Fed. Cir. 1991).

435. *Id.* at 1509.

436. *Id.*

437. *Id.*

438. *Id.* at 1510.

439. *Filmtec*, 19 USPQ2D at 1510.

at the non-profit research organization, the Government could have no more than equitable title to the patent, which equitable title could not be asserted as a defense by the alleged infringer.⁴⁴⁰ The district court issued a preliminary injunction against the alleged infringer, and the alleged infringer appealed.

The Federal Circuit viewed the issue on appeal as not who should ultimately be held to have title to the patent, but instead whether the plaintiff had made a sufficient showing to establish reasonable likelihood of success on the merits, which included a showing that title to the patent was held by the plaintiff.⁴⁴¹

The Federal Circuit agreed with the alleged infringer that if the subject matter of the patent had been invented by the inventor during his employment with the non-profit research organization, and if the inventor had granted the non-profit research organization rights in the invention made during his employment, then the inventor had nothing to give to the plaintiff and the purported assignment to the plaintiff was a nullity.⁴⁴² Consequently, the plaintiff would lack both title to the patent and standing to bring the present action.⁴⁴³

However, the record did not indicate whether the employment agreement between the inventor and the non-profit research organization either granted or required the inventor to grant to the non-profit research organization the rights to the patented invention.⁴⁴⁴ The Federal Circuit was therefore unable to determine who held legal title to the patent and was unable to determine if the plaintiff could make a sufficient legal showing to establish the likelihood of success necessary to support a preliminary injunction.⁴⁴⁵

Because the record left serious doubts as to who had title to the patent, the Federal Circuit concluded that the plaintiff had failed to establish a reasonable likelihood of success on the merits on the title issue. Consequently, the Federal Circuit vacated the grant of the preliminary injunction and remanded to the district court for further proceedings.⁴⁴⁶

440. *Id.* at 1511.

441. *Id.*

442. *Id.*

443. *Id.* at 1512.

444. *Filmtec*, 19 USPQ2D at 1512.

445. *Id.*

446. *Id.* at 1513.

XII. DAMAGES - 35 U.S.C. § 284

A. *A Party Seeking to Recover Money Damages for Patent Infringement Must Have Held Legal Title to the Patent During the Time of the Infringement*

The assignee of the subject patent in the case of *Arachnid, Inc. v. Merit Industries, Inc.*⁴⁴⁷ had entered into a consulting agreement in 1980. The consulting agreement provided that any inventions conceived by the consultant's employees in the course of the project covered by the agreement would be the property of the patent assignee, and all rights to the invention "will be assigned" by the consultant to the patent assignee.⁴⁴⁸

In November, 1982, several months after the consulting agreement was terminated, the consultant's employees filed an application for the subject patent. However, instead of assigning the patent application to the patent assignee, the consultant's employees assigned the patent application to the consultant.⁴⁴⁹

In April, 1983, the patent assignee sued the consultant for breach of the 1980 consulting agreement, seeking an assignment of all right, title, and interest in the patent application (from which the subject patent had subsequently issued) that had been filed by the consultant's employees.⁴⁵⁰

In April, 1987, the district court declared the patent assignee to have been and to be the lawful owner of all right, title, and interest in and to the patented invention since the conception of the invention.⁴⁵¹ The district court ordered the consultant to assign all its right, title, and interest in the patent to the patent assignee.⁴⁵²

In October, 1987, in accordance with the district court order, the consultant executed an assignment of all of its right, title, and interest in and to the patent to the patent assignee.⁴⁵³ The assignment did not include any assignment of the right to recover for past infringement.⁴⁵⁴

Meanwhile, in May, 1985, the consultant had granted a nonexclusive license to practice the patented invention to the alleged in-

447. 939 F.2d 1574, 19 USPQ2D 1513 (Fed. Cir. 1991).

448. *Id.* at 1515.

449. *Id.*

450. *Id.*

451. *Arachnid*, 19 USPQ2D at 1516.

452. *Id.*

453. *Id.*

454. *Id.*

fringer.⁴⁵⁵ Beginning in December, 1985, and ending in June, 1986, the alleged infringer had manufactured and sold a device which admittedly fell within the scope of the patent claims.⁴⁵⁶

In June, 1989, the patent assignee sued the alleged infringer in district court, seeking to recover money damages based upon the alleged infringer's sales of the accused device in the 1985-86 period.⁴⁵⁷ The patent assignee moved for a directed verdict on the issue of infringement. The district court granted the patent assignee's motion, directing a verdict of infringement and assessing money damages.⁴⁵⁸ The alleged infringer appealed from the district court's final judgment.

On appeal, the issue was whether the patent assignee had standing to sue for money damages for infringement that occurred in 1985-86.⁴⁵⁹

The alleged infringer argued that the patent assignee did not have standing to sue for an infringement that had occurred in 1985-86.⁴⁶⁰ The alleged infringer asserted that until October 1987 (when the consultant assigned the patent to the patent assignee), the patent assignee had only "equitable title" to the patent, not "legal title," and that such equitable title alone was not sufficient to confer standing to sue for money damages for infringement.⁴⁶¹

The patent assignee argued that it had acquired all legal and equitable rights to the patented invention when the consultant signed the consulting agreement in 1980.⁴⁶² The patent assignee had therefore always been the legal and equitable owner of the patented invention, and on that basis the patent assignee had standing to sue the alleged infringer for the infringement occurring in 1985-86.⁴⁶³

The Federal Circuit noted initially that an action to recover money damages for patent infringement is an action "at law," rather than an action "in equity."⁴⁶⁴ The general rule is that one seeking to recover money damages for patent infringement must have held the legal title to the patent during the time of the

455. *Arachnid*, 19 USPQ2D at 1515.

456. *Id.*

457. *Id.*

458. *Id.* at 1516.

459. *Id.*

460. *Arachnid*, 19 USPQ2D at 1516.

461. *Id.*

462. *Id.*

463. *Id.*

464. An example of an action "in equity" is an action seeking an injunction for patent infringement.

infringement.⁴⁶⁵

The Federal Circuit found that the 1980 consulting agreement was merely an agreement to assign, rather than an assignment.⁴⁶⁶ The statement in the agreement that all rights to inventions developed during the consulting period "will be assigned" to the patent assignee was not a present assignment of an existing invention and was not effective to transfer all legal rights to the patent assignee. The patent assignee therefore did not obtain legal title to the patent until October 1987, when the consultant executed an assignment of all of its right, title, and interest in and to the patent to the patent assignee.⁴⁶⁷

The Federal Circuit further found that the 1987 district court order decreeing the patent assignee to have been the owner of the invention since the invention's conception may have validated the patent assignee's right to seek equitable relief against the consultant. However, the 1987 district court order did not retroactively divest the consultant of legal title to the patent during the 1985-86 timeframe and revest that legal title in the patent assignee for standing purposes.⁴⁶⁸

Therefore, the Federal Circuit concluded that the district court had erred in directing a verdict of infringement in favor of the patent assignee, and reversed the judgment of the district court.⁴⁶⁹

B. *A Reasonable Royalty Under 35 U.S.C. § 284 Is Not Restricted to a Specific Figure Put Forth By One of the Parties*

The accused product in the case of *SmithKline Diagnostics, Inc. v. Helena Laboratories Corporation*⁴⁷⁰ had been held to infringe

465. *Crown Die & Tool Co. v. Nye Tool & Mach. Works*, 261 U.S. 24, 67 L. Ed. 516, 43 S. Ct. 254 (1923). An exception to the general rule is recognized where the assignment of a patent is coupled with an assignment of a right of action for past infringement. Another exception to the general rule has been recognized which confers standing upon non-patent owners to join in infringement suits as co-plaintiffs with the patentee; see, e.g., *Kalman v. Berlyn Corp.*, 914 F.2d 1473, 16 USPQ2D 1093 (Fed. Cir. 1990) (sole licensee with clearly defined nexus to patentee); *Weinar v. Rollform Inc.*, 744 F.2d 797, 223 USPQ 369 (Fed. Cir. 1984) (exclusive vendor of patented product), *cert. denied*, 470 U.S. 1084, 105 S. Ct. 1844, 85 L. Ed. 2d 143 (1985).

466. *Arachnid*, 19 USPQ2D at 1518.

467. *Id.* at 1519.

468. *Id.*

469. *Id.* at 1519.

470. 926 F.2d 1161, 17 USPQ2D 1922 (Fed. Cir. 1991). See also *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F.2d 878, 891, 8 USPQ2D 1468, 1479 (Fed. Cir. 1988).

the patent.⁴⁷¹ The district court had concluded that the patentee had failed to establish the requirements for a damage award based upon lost profits.⁴⁷²

The district court turned to the alternative damage remedy available under 35 U.S.C. § 284, namely, the calculation of damages based upon a "reasonable royalty".⁴⁷³ The district court entered a "reasonable royalty" damage award based upon a 25% royalty for the infringer's sales of infringing goods.⁴⁷⁴

The patentee appealed the judgment of the district court, urging that the district court had wrongly denied the patentee a greater amount calculated on the basis of the patentee's lost profits. The infringer cross-appealed, asserting that the district court's award based on the 25% royalty figure could not be upheld because this figure was not specifically advocated by either party.⁴⁷⁵ The infringer asserted that the district court should have entered a "reasonable royalty" damage award based on only a 3% royalty figure, since this was the royalty figure at which the infringer had licensed other, similar products.⁴⁷⁶

On appeal, the Federal Circuit noted that the amount of a prevailing party's damages is a finding of fact.⁴⁷⁷ Consequently, if the amount of a prevailing party's damages is fixed by the district court, then the damage award is reviewed in accordance with the "clearly erroneous" standard of Fed. R. Civ. P. 52(a).⁴⁷⁸

The Federal Circuit then affirmed the district court's finding that the patentee had failed to prove, by a preponderance of the evidence, its entitlement to recover its lost profits as actual damages.⁴⁷⁹

With respect to the district court's determination of a reasonable royalty, the Federal Circuit ruled that a district court is not restricted in finding a reasonable royalty to a specific figure put forth by one of the parties.⁴⁸⁰ The district court may reject the figures proffered by the parties and may substitute an intermediate figure as a matter of the district court's judgment based upon all of

471. *SmithKline*, 17 USPQ2D at 1923.

472. *Id.* at 1924.

473. *Id.*

474. *SmithKline Diagnostics Inc. v. Helena Laboratories Corp.*, 12 USPQ2D 1375 (E.D. Tex. 1989).

475. *SmithKline*, 17 USPQ2D at 1924.

476. *Id.*

477. *Id.*

478. *Id.* at 1925.

479. *Id.*

480. *Radio Steel & Mfg. Co.*, 788 F.2d at 1556-57, 229 USPQ at 433 (Fed. Cir. 1986).

the evidence.⁴⁸¹

In *SmithKline*, the record showed that the infringer had entered licenses for products similar to the infringing product at royalty rates as low as 3% and 5%.⁴⁸² However, the record also showed that the infringer had competed with lower priced competitors than the patentee. Furthermore, the evidence showed that the patented product had achieved immediate commercial success, that the patented product had satisfied a long felt need, that the patentee had never licensed the patented technology, and that the patentee had intended to maintain its exclusivity of the patented technology by refusing to grant licenses under the patent.⁴⁸³

The Federal Circuit concluded that the finding of 25% as a reasonable royalty had been based on all of the evidence and was not clearly erroneous. Consequently, the Federal Circuit affirmed the 25% royalty as reasonable.⁴⁸⁴

C. Lost Profit Damages Must Be Based on Infringing Sales

The subject patent in the case of *Standard Havens Products, Inc. v. Gencor Industries, Inc.*⁴⁸⁵ was directed to a "counterflow" method of producing asphalt compositions.⁴⁸⁶ The patentee had charged the alleged infringer with contributing to or inducing infringement of the patent via the sale of the alleged infringer's asphalt-producing "Ultraplant," which plant allegedly performed the claimed "counterflow" method.⁴⁸⁷

The district court found that the alleged infringer had contributed to and induced infringement of the patent, and that the patentee had suffered lost profit damages.⁴⁸⁸ The district court based the amount of lost profit damages upon the alleged infringer's sale of ten asphalt plants.⁴⁸⁹ Judgment was entered against the alleged infringer, and the alleged infringer appealed.

On appeal, the alleged infringer argued that the damage award should be vacated because the patentee had never bid on two of the ten asphalt plant sales used to calculate the damage award.⁴⁹⁰

481. *SmithKline*, 17 USPQ2D at 1926.

482. *Id.* at 1928.

483. *Id.*

484. *Id.* at 1928.

485. 953 F.2d 1360, 21 USPQ2D 1321 (Fed. Cir. 1991).

486. *Id.* at 1323.

487. *Id.* at 1324.

488. *Id.* at 1325.

489. *Id.*

490. *Standard Havens*, 21 USPQ2D at 1325.

However, the Federal Circuit found that there were no acceptable noninfringing substitutes for asphalt plants that used the patented "counterflow" process.⁴⁹¹ Consequently, it was not of controlling significance that the patent owner did not bid on every one of the infringing sales, since this fact did not show that the patentee could not or would not have made those sales if the infringer had not infringed.⁴⁹² Thus, the Federal Circuit did not view the fact that the patentee had not bid on two of the ten asphalt plant sales included in the damage award as a basis for overturning the award.⁴⁹³

The alleged infringer further argued that four of the ten asphalt plant sales were improperly included in the damage award, since three of the sales were of noninfringing asphalt plants, and one sale had been made to a foreign customer located in England.⁴⁹⁴

Regarding the three noninfringing asphalt plant sales, the patentee argued that the alleged infringer's bids for those sales had included the infringing "counterflow" asphalt plant, and it was only after the bid had been accepted that the alleged infringer substituted a noninfringing "parallel flow" asphalt plant.⁴⁹⁵ Because of that substitution, the patentee contended that it had lost sales of its "counterflow" asphalt plant.⁴⁹⁶ However, because an infringing "counterflow" asphalt plant had never actually been sold, the Federal Circuit concluded that there had been no direct infringement and, therefore, no contributory infringement.⁴⁹⁷

Regarding the sale to the foreign customer, the patentee asserted that the sale had been made in the U.S. However, the Federal Circuit observed that the patent claimed a method for producing asphalt, not an apparatus for implementing that process. Consequently, the sale in the U.S. of the unpatented apparatus alone did not make the alleged infringer a contributory infringer of the patented method.⁴⁹⁸

Moreover, there was no evidence that the foreign customer had used the asphalt plant in the U.S., or that the foreign customer had shipped products back to the U.S. made abroad by the patented

491. *Id.*

492. *Gyromat Corp. v. Champion Spark Plug Co.*, 735 F.2d 549, 222 USPQ 4 (Fed. Cir. 1984).

493. *Standard Havens*, 21 USPQ2D at 1326.

494. *Id.* at 1328.

495. *Id.*

496. *Id.* at 1329.

497. *Porter v. Farmers Supply Serv., Inc.*, 790 F.2d 882, 884, 229 USPQ 814, 815 (Fed. Cir. 1986).

498. *Standard Havens*, 21 USPQ2D at 1330.

process.⁴⁹⁹ Consequently, infringement by the foreign customer had not been shown and, in the absence of direct infringement, there can be no inducement of infringement or contributory infringement.⁵⁰⁰

The Federal Circuit therefore vacated the patent damage award and remanded the case for redetermination of the proper award for lost profits based on the six infringing asphalt plant sales.⁵⁰¹

D. *A Patent Owner Establishing All Four Panduit Requirements Has Sustained the Burden of Proving Entitlement to Lost Profits for All Infringing Sales*

Under 35 U.S.C. § 284, a district court is required to award damages adequate to compensate the patent owner for infringement, but in no event less than a reasonable royalty. Generally, in determining whether a patent owner is entitled to obtain damages for lost profits caused by the infringement, the district court must conclude (1) that the patent owner would have made the sales of the patented product but for the occurrence of the infringement, and (2) that proper evidence supporting the computation of lost profits was presented at trial.⁵⁰²

The only specific test approved by the Federal Circuit in determining whether a patent owner is entitled to obtain damages for lost profits caused by the infringement was introduced in the case of *Panduit Corp. v. Stahl Brothers Fibre Works, Inc.*⁵⁰³ The *Panduit* test has four requirements. To obtain damages for lost profits, the patent owner must prove (1) a demand for the patented product, (2) the marketing and manufacturing capability to exploit the demand, (3) an absence of acceptable noninfringing substitutes for the patented product, and (4) the amount of profit which the patent owner would have made.⁵⁰⁴

During the accounting phase of litigation in the case of *Kaufman Company, Inc. v. Lantech, Inc.*⁵⁰⁵ the district court, applying

499. *Id.*

500. *Id.* at 1331.

501. *Id.* at 1332.

502. *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 863, 226 USPQ 402, 409 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1016, 89 L.Ed. 2d 312, 106 S.Ct. 1197 (1986).

503. 575 F.2d 1152, 197 USPQ 726 (6th Cir. 1978).

504. *Id.* at 730.

505. 926 F.2d 1136, 17 USPQ2D 1828 (Fed. Cir. 1991). The Federal Circuit had previously affirmed a judgment of willful infringement. *Kaufman Co. v. Lantech, Inc.*, 807 F.2d 970, 1 USPQ2D 1202 (Fed. Cir. 1986).

the *Panduit* test, had concluded that the patent owner was entitled to lost profit damages for only 8 of 44 infringing sales.⁵⁰⁶ The district court had concluded that lost profit damages should not be awarded for 36 of the infringing sales because the third *Panduit* element had not been satisfied for these sales (i.e., the patent owner had failed to show an absence of acceptable noninfringing substitutes for these 36 infringing sales).⁵⁰⁷ This finding was based on the fact that the patent owner had presented specific evidence of the absence of acceptable noninfringing substitutes for 8 of the infringing sales, but had failed to present specific evidence of the absence of acceptable noninfringing substitutes for the remaining 36 infringing sales.⁵⁰⁸ Because the district court found that acceptable noninfringing substitutes for the patented product did exist, the court denied lost profit damages for 36 of the 44 infringing sales.⁵⁰⁹

On appeal, a threshold issue was whether the district court had applied the correct rule of law in finding that there existed acceptable noninfringing substitutes for the patented product.⁵¹⁰

The Federal Circuit noted that to be deemed acceptable, a noninfringing substitute must not have a disparately higher price than, or possess characteristics significantly different from, the patented product.⁵¹¹ In *Kaufman*, the allegedly noninfringing substitutes did not possess all of the beneficial characteristics of the patented product, nor were they priced as low as the patented product.⁵¹² The district court therefore erred when it concluded that the allegedly noninfringing substitutes were "acceptable" noninfringing substitutes.⁵¹³ The district court should have found that there were no acceptable noninfringing substitutes, and therefore should have found that all four factors of the *Panduit* test had been satisfied.⁵¹⁴

The Federal Circuit further ruled that because the patent owner had established all four *Panduit* requirements, the patent owner had sustained the burden of proving entitlement to lost profits for all infringing sales.⁵¹⁵ In other words, because all four

506. *Kaufman*, 17 USPQ2D at 1829.

507. *Id.*

508. *Id.*

509. *Id.* at 1830.

510. *Id.*

511. *Gyromat Corp. v. Champion Spark Plug Co.*, 735 F.2d 549, 553, 222 USPQ 4, 7 (Fed.Cir. 1984).

512. *Kaufman*, 17 USPQ2D at 1830.

513. *Id.*

514. *Id.* at 1832.

515. *See, e.g., Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp.*, 739 F.2d 604, 616, 222 USPQ 654, 663 (Fed. Cir.), *cert. denied*, 469 U.S. 1038, 83 L. Ed. 2d 405, 105 S. Ct.

Panduit requirements were satisfied, it was reasonable to infer that the patent owner probably would have made all 44 of the infringing sales but for the occurrence of the infringement.⁵¹⁶ The burden should then be placed upon the infringer to show that it is unreasonable to infer that some or all of the infringing sales probably caused the patent owner to suffer lost profits. Any doubts regarding the calculatory precision of the damage amount are resolved against the infringer.⁵¹⁷

According to the Federal Circuit, the reasonableness of the inference that the patent owner probably would have made all 44 of the infringing sales was not negated by evidence showing a customer preference for the infringer's services over those of the patent owner.⁵¹⁸ Nor was the reasonableness of the inference negated by the patent owner's admission that it would not have competed with the infringer for every one of the 44 infringing sales.⁵¹⁹

The Federal Circuit reversed and remanded this case for the district court to calculate and award to the patent owner those profits lost on all 44 infringing sales.⁵²⁰

E. *Damages May Not Be Increased Under the Second Paragraph of 35 U.S.C. § 284 to Rectify a Perceived Inadequacy in an Actual Damage Award*

The infringer in the case of *Beatrice Foods Co. v. New England Printing and Lithographing Co.*⁵²¹ had intentionally destroyed evidence, thereby hindering the patentee in proving infringement and making it more difficult to accurately determine the actual damages. The district court decided to triple the damage award, explaining that the damage award was tripled not as a penalty, but to provide the patentee with adequate compensation for the infringement.⁵²²

516 (1984). The patent owner is only required to show that there was a "reasonable probability" that it would have made the infringing sales but for the occurrence of the infringement. The patent owner is not required to negate every possibility that a purchaser might not have bought another product other than the patented product absent the infringement. *Gyromat Corp. v. Champion Spark Plug Co.*, 735 F.2d 549, 554, 222 USPQ 4, 8 (Fed. Cir. 1984).

516. The inference that the patent owner probably would have made all of the 44 infringing sales but for the occurrence of the infringement was also compelled by the fact that the patent owner and the infringer were the only two suppliers competing in the market. *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065, 219 USPQ 670, 675 (Fed.Cir. 1983).

517. *Id.*

518. *Kaufman*, 17 USPQ2D at 1832.

519. *Id.*

520. *Id.*

521. 923 F.2d 1576, 17 USPQ2D 1553 (Fed. Cir. 1991).

522. *Id.*

The principal issue on appeal was whether the district court had improperly tripled the damages on the theory that the increased award was necessary to adequately compensate the patentee for the infringement.⁵²³

The Federal Circuit noted that the provision of the patent laws governing the award of damages for infringement is 35 U.S.C. § 284.⁵²⁴ The first paragraph of 35 U.S.C. § 284 requires the district court to award damages "adequate to compensate for the infringement." The second paragraph of 35 U.S.C. § 284 authorizes the district court to increase the damages up to threefold. The statute does not state the basis upon which a district court may increase damages. However, case authority states that increased damages may be awarded only as a penalty for an infringer's willful infringement or bad faith.⁵²⁵

The Federal Circuit held that the adequacy of the damage award must be measured by actual damages pursuant to the first paragraph of § 284, rather than by increased damages pursuant to the second paragraph of § 284.⁵²⁶ If, as in *Beatrice*, the infringer's own conduct makes it difficult or impossible for the patentee to accurately determine the actual damages, then a district court may resolve all doubts against the infringer and determine the actual damages based upon the best available evidence.⁵²⁷ However, a district court may not increase the actual damage award under 35 U.S.C. § 284, second paragraph, in order to rectify what the district court views as an inadequacy in the actual damage award.⁵²⁸ A district court may increase the actual damage award under 35 U.S.C. § 284, second paragraph, only as a penalty for an infringer's willful infringement or bad faith.⁵²⁹

The Federal Circuit in *Beatrice* therefore affirmed the judgment of the district court insofar as it awarded actual damages, but

523. The case was before the district court on remand from the Federal Circuit for the purpose of determining the patentee's damages. See *Beatrice Foods Co. v. New England Printing and Lithographing Co.*, 899 F.2d 1171, 1176, 14 USPQ2D 1020, 1024 (Fed. Cir. 1990).

524. *Beatrice*, 17 USPQ2D at 1554.

525. *Yarway Corp. v. Eur-Control USA, Inc.*, 775 F.2d 268, 277, 227 USPQ 352, 358 (Fed. Cir. 1985); *Lam, Inc. v. Johns-Manville Corp.*, 668 F.2d 462, 474-75, 213 USPQ 1061, 1070-71 (10th Cir.), cert. denied, 456 U.S. 1007, 73 L.Ed. 2d 1302, 102 S. Ct. 2298 (1982).

526. *Beatrice*, 17 USPQ2D at 1556.

527. *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065, 219 USPQ 670, 675 (Fed. Cir. 1983).

528. *Beatrice*, 17 USPQ2D at 1557.

529. *Id.*

vacated the judgment insofar as it awarded increased damages.⁵³⁰

F. *A Reduction of Lost Profit Damages Can Not Be Based Solely on Market Share*

The district court in the case of *Uniroyal, Inc. v. Rudkin-Wiley Corp.*⁵³¹ had found the infringer liable for patent infringement. In assessing damages, the district court had found that no acceptable non-infringing substitutes for the patented product existed in the relevant market.⁵³² The district court had further found that, in the absence of the infringing sales, the patentee would have possessed an 80% market share.⁵³³ The district court therefore awarded the patentee damages for lost profits on only 80% of the infringing sales.⁵³⁴ The patentee appealed the judgment on the grounds that the district court had erred as a matter of law in reducing the damage award by 20%.⁵³⁵

On appeal, the Federal Circuit agreed that the district court had erred. The Federal Circuit stated that the mere existence of a competing product in the market does not necessarily make that product an "acceptable substitute." For example, a competing product which lacks the advantages of the patented product is not an acceptable substitute to a customer seeking those advantages.⁵³⁶ Consequently, merely because a share of the market is held by competitors, it does not necessarily follow that acceptable non-infringing substitutes exist in the market.⁵³⁷

The Federal Circuit further stated that in determining whether a reduced damage award for lost profits is justified, the controlling issue is not whether there are other competitors in the market, but instead whether such competitors sell an acceptable non-infringing substitute.⁵³⁸ The district court had found that there were no competitors selling an acceptable non-infringing substitute, and this finding was not clearly erroneous.⁵³⁹ Thus, the patentee should

530. *Id.* at 1557.

531. 939 F.2d 1540, 19 USPQ2D 1432 (Fed. Cir. 1991).

532. *Id.* at 1434.

533. *Id.*

534. See *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 721 F. Supp. 28, 13 USPQ2D 1192 (Conn. June 26, 1989, Aug. 21, 1989).

535. *Id.* at 1435.

536. *Id.* at 1436.

537. *TWM Mfg. Co. v. Dura Corp.*, 789 F.2d 895, 901, 229 USPQ 525, 529 (Fed. Cir.), *cert. denied*, 479 U.S. 852, 93 L. Ed. 2d 117, 107 S. Ct. 183 (1986); *Radio Steel & Mfg. Co. v. MTD Prods., Inc.*, 788 F.2d 1554, 1556, 229 USPQ 431, 432-33 (Fed. Cir. 1986).

538. *Uniroyal*, 19 USPQ2D at 1437.

539. *Id.*

have been awarded a profit on all of the infringing sales.⁵⁴⁰ The district court's reduction of lost profits based solely on market share was inconsistent with the finding of an absence of acceptable non-infringing substitutes.⁵⁴¹

The Federal Circuit therefore vacated and remanded for the entry of a judgment for damages reflecting the patentee's lost profits on all of the infringing sales.⁵⁴²

G. A District Court Determination Denying Enhanced Damages May Not Be Overturned Absent A Clear Showing of Abuse of Discretion

After finding infringement, the district court in the case of *State Industries, Inc. v. Mor-Flo Industries, Inc.*⁵⁴³ had awarded the patentee lost profits on some infringing sales and a royalty on the remaining sales.⁵⁴⁴ The district court had also found that the infringement had not been willful and had denied enhanced damages under 35 U.S.C. § 284.⁵⁴⁵

The Federal Circuit had affirmed the district court's judgment insofar as it had awarded lost profits and a royalty.⁵⁴⁶ The Federal Circuit had vacated the district court's judgment insofar as it had denied increased damages, and remanded to the district court to reconsider whether a finding of willful infringement and enhanced damages was justified.⁵⁴⁷

On remand, the district court concluded that a finding of willful infringement and enhanced damages was not justified, and entered an order denying them.⁵⁴⁸ Because the district court's order left its damage award unchanged, the patentee appealed.

The patentee argued on appeal that the district court's failure to find willfulness was clearly erroneous, and that the district court had erred in not awarding enhanced damages.⁵⁴⁹

On appeal, the Federal Circuit noted that a district court's analysis of whether to increase damages is a two-step process. First, the district court must determine whether willful infringement has

540. *Id.*

541. *Id.* at 1438.

542. *Id.* at 1439.

543. 948 F.2d 1573, 20 USPQ2D 1738 (Fed. Cir. 1991).

544. *Id.* at 1739.

545. *Id.*

546. *Id.*

547. *Id.* at 1740.

548. *State Industries*, 20 USPQ2D at 1740.

549. *Id.*

been proven. Second, if the district court finds that willful infringement has been proven, then it must still determine whether or not, under the totality of the circumstances, increased damages are warranted.⁵⁵⁰ This determination is committed to the sound discretion of the district court.⁵⁵¹ A finding of willfulness, though a sufficient basis for an award of enhanced damages, does not compel such an award.⁵⁵² The district court's determination may not be overturned absent a clear showing of abuse of discretion.⁵⁵³

The Federal Circuit found that the patentee in *State Industries* was unable to point to any basis on which clear error in the district court's willfulness finding could be shown.⁵⁵⁴ Moreover, even if the finding of no willfulness was overturned, that would not mandate reversal of the district court's discretionary decision to deny enhanced damages.⁵⁵⁵

Because the district court did not abuse its discretion in denying enhanced damages, the Federal Circuit affirmed. And because the Federal Circuit found the patentee's appeal to be frivolous as filed and as argued, the Federal Circuit imposed sanctions pursuant to Fed.R.App.P. 38.⁵⁵⁶

XIII. ATTORNEY FEES - 35 U.S.C. § 285

A. *Restitution of Fee Award Under 35 U.S.C. § 285 May Be Inferred From Appellate Opinion*

The district court in the case of *Sun-Tek Industries, Inc. v. Kennedy Sky Lites, Inc.*⁵⁵⁷ had originally held that no "exceptional case" under 35 U.S.C. § 285 had been established, and had entered final judgment.⁵⁵⁸ Seven months later, the District Court reversed its determination and entered an amended final judgment which awarded the plaintiff attorney fees under 35 U.S.C. § 285.⁵⁵⁹ The defendant appealed to the Federal Circuit and challenged the district court's authority to reverse its original final judgment and

550. *Id.*

551. *Id.*

552. *Modine Mfg. Co. v. Allen Group, Inc.*, 917 F.2d 538, 542-43, 16 USPQ2d 1622, 1625-26 (Fed. Cir. 1990), *cert. denied*, 111 S. Ct. 2017, 114 L. Ed. 2d 103 (1991).

553. *State Industries*, 20 USPQ2D at 1740.

554. *Id.* at 1742.

555. *Id.*

556. *Id.*

557. 929 F.2d 676, 18 USPQ2D 1332 (Fed. Cir. 1991).

558. *Id.* at 1333.

559. *Id.*

enter an amended final judgment awarding attorney fees.⁵⁶⁰

While that appeal had been pending, the defendant had been unable to maintain the bond required by the district court in order to stay execution of the amended final judgment.⁵⁶¹ As a result, the plaintiff had satisfied the amended final judgment against the defendant through execution on the proceeds of a sale of the defendant's assets.⁵⁶²

Thereafter, the Federal Circuit ruled that the district court had been without jurisdiction and authority to reverse its original final judgment.⁵⁶³ The Federal Circuit vacated that portion of the district court's amended final judgment which had awarded attorney fees to the plaintiff.⁵⁶⁴

The district court then determined that the mandate of the Federal Circuit did not include any stated requirement to order the plaintiff to make restitution of the attorneys' fees awarded in the amended final judgment.⁵⁶⁵ The district court therefore ruled that (1) the plaintiff did not have to repay the attorney fees it had received pursuant to the amended final judgment, and (2) the proceedings in the district court following the amended final judgment supported a new finding of an "exceptional case" under 35 U.S.C. § 285 entitling the plaintiff to additional attorney fees.⁵⁶⁶ The defendant appealed both rulings of the district court.

On appeal, the Federal Circuit acknowledged that the district court may have been technically correct in stating that the Federal Circuit's mandate did not include an explicit requirement to order restitution.⁵⁶⁷ However, the Federal Circuit's prior opinion had held that the district court did not have authority to amend its original final judgment, and that the district court's reversal of the original final judgment had been improper.⁵⁶⁸ Consequently, the award of attorney fees under 35 U.S.C. § 285 after the original final judgment had been entered had been a nullity.⁵⁶⁹ The Federal Circuit concluded that, under these circumstances, the district court had

560. *Id.*

561. *Id.*

562. *Sun-Tek*, 18 USPQ2D at 1333.

563. *Id.* at 1333-34.

564. *See Sun-Tek Indus., Inc. v. Kennedy Sky Lites, Inc. et al.*, 848 F.2d 179, 6 USPQ2D 2017 (Fed. Cir. 1988), *cert. denied*, 488 U.S. 1009, 102 L. Ed. 2d 784, 109 S. Ct. 793 (1989).

565. *Sun-Tek*, 18 USPQ2D at 1334.

566. *Id.*

567. *Id.*

568. *Id.*

569. *Id.*

been given more than sufficient guidance to be able to infer the Federal Circuit's intention to order restitution.⁵⁷⁰ Thus, under the Federal Circuit's previous holding that attorney fees were improperly awarded, the Federal Circuit required the plaintiff to repay all it had collected in the grant of attorney fees, plus interest to the date of repayment.⁵⁷¹ With respect to the district court's award of additional attorney fees for the defendant's post-judgment conduct, the Federal Circuit observed that a district court may properly award attorney fees under § 285 to prevent "gross injustice" when a party has litigated vexatiously.⁵⁷²

The district court had based its award of additional attorney fees on the defendant's post-judgment litigation tactics, including the defendant's violation of the bond reduction order and attempts to defeat the plaintiff's execution on the amended final judgment.⁵⁷³ The district court had evaluated the defendant's post-judgment conduct in light of the defendant's previous litigation tactics.⁵⁷⁴

The Federal Circuit found that it was proper for the district court to take into consideration the pattern established by the defendant during the trial in determining whether the defendant's post-judgment conduct had been vexatious.⁵⁷⁵ The Federal Circuit could not say that the district court's conclusion that the defendant's post-judgment actions were vexatious had been improper.⁵⁷⁶ Accordingly, the Federal Circuit found that the district court's award of additional attorney fees for post-judgment vexatious conduct had not been an abuse of discretion.⁵⁷⁷

XIV. TIME LIMITATION ON DAMAGES - 35 U.S.C. § 286

A. *A Patentee's Delay In Bringing Suit Does Not Alone Create a Presumption of Prejudice*

The patentee in the case of *A.C. Aukerman Company v. R.L. Chaides Construction Co.*⁵⁷⁸ had advised the accused infringer of the

570. *Sun-Tek*, 18 USPQ2D at 1334.

571. *Id.*

572. See *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1552, 13 USPQ2D 1301, 1304 (Fed. Cir. 1989); *Machinery Corp. of America v. Gullfiber AB*, 774 F.2d 467, 227 USPQ 368 (Fed. Cir. 1985); *Rohm & Haas Co. v. Crystal Chem. Co.*, 736 F.2d 688, 222 USPQ 97 (Fed. Cir. 1984).

573. *Sun-Tek*, 18 USPQ2D at 1335.

574. *Id.*

575. *Id.*

576. *Id.*

577. *Id.*

578. 18 USPQ2D 1618 (Fed. Cir. 1991).

alleged infringement in 1979.⁵⁷⁹ Essentially no further contact had occurred between the parties for approximately eight and one-half years.⁵⁸⁰ In 1988 the patentee filed suit for infringement.

The accused infringer responded by raising the defenses of laches and estoppel. The accused infringer asserted that the patentee's delay in filing suit had created a presumption that the delay was unreasonable and prejudicial, and the burden of proving the reasonableness of the delay or lack of prejudice was thereby shifted to the patentee.⁵⁸¹

The district court granted summary judgment in favor of the accused infringer, holding that the doctrines of laches and estoppel blocked the patentee's recovery of any damages.⁵⁸²

On appeal, the Federal Circuit noted that 35 U.S.C. § 286 permits a patentee to sue for damages even though the first act of infringement had occurred more than six years prior to filing suit.⁵⁸³ However, in such a case, any damage award is limited to acts of infringement which occurred within the preceding six years.⁵⁸⁴ The Federal Circuit further observed that the issue of what presumptions arise from a patentee's delay exceeding the six year period of § 286 is a matter about which there is some confusion.⁵⁸⁵

In the case of *Cornetta v. United States*⁵⁸⁶ (a non-patent case), the Federal Circuit, sitting *en banc*, emphasized that delay alone does not constitute laches.⁵⁸⁷ The Federal Circuit rejected the idea that a defendant asserting a laches defense can rely on a presumption of prejudice, or shift the burden to the plaintiff to show lack of prejudice, merely because the delay is long.⁵⁸⁸

However, in the case of *Leinoff v. Louis Milona & Sons, Inc.*,⁵⁸⁹ the Federal Circuit stated that a delay of more than six years in bringing an infringement action after the infringement is "noticed" is a presumptively unreasonable delay, and a patentee who waits for

579. *Id.* at 1625.

580. *Id.*

581. *See, for example*, *Jamesbury Corp. v. Litton Indus. Prods.*, 839 F.2d 1544, 5 USPQ2d 1779 (Fed. Cir.), *cert. denied*, 488 U.S. 828 (1988).

582. *A.C. Aukerman*, 18 USPQ2D at 1625.

583. *Id.* at 1622.

584. "Except as otherwise provided by law, no recovery shall be had for any infringement committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action." 35 U.S.C. § 286.

585. *A.C. Aukerman*, 18 USPQ2D at 1622.

586. 851 F.2d 1372, 1375 (Fed. Cir. 1988).

587. *Id.*

588. *Id.*

589. 726 F.2d 734, 220 USPQ 845 (Fed. Cir. 1984).

more than six years before filing suit must explain the delay.⁵⁹⁰ If the patentee fails to explain the delay, then a district court may find that the period of time alone to be sufficient evidence of undue delay.⁵⁹¹ Moreover, a delay of six years raises a presumption of material injury, and places on the patentee the additional burden of proving a lack of injury to the infringer caused by the delay.⁵⁹²

In *Aukerman*, the Federal Circuit adopted the rule in *Cornetta* and specifically rejected the notion that a presumption of prejudice arises due to the mere fact that the patentee delayed bringing suit.⁵⁹³ The Federal Circuit ruled that prejudice requires a showing that the patentee's delay was both unreasonable and inexcusable.⁵⁹⁴ Furthermore, the burden of proof in establishing the defenses of laches and estoppel remains with the accused infringer who alleges the defenses.⁵⁹⁵

The Federal Circuit therefore concluded that the district court had erred in placing the burden on the patentee to rebut the presumption of prejudice, and had erred in concluding that the patentee was barred by the defenses of laches or estoppel.⁵⁹⁶ Accordingly, the Federal Circuit vacated the grant of summary judgment and remanded.

(Subsequent to rendering the above decision in the case of *A.C. Aukerman Company v. R.L. Chaides Construction Co.*, the Federal Circuit vacated the decision and granted a rehearing.)⁵⁹⁷

XV. REQUEST FOR REEXAMINATION - 35 U.S.C. § 302

A. *Extrinsic Evidence May Be Considered In a Reexamination to Explain the Meaning of a Reference*

The subject patent in the case of *In re Baxter Travenol Labs*⁵⁹⁸ was directed to a system for collecting, processing and storing components of blood. The claimed invention included a blood bag containing DEHP, a plasticizer.⁵⁹⁹

The patentee had filed a request for reexamination based upon a prior art article, written by an employee of the patentee, which

590. *Id.*

591. *Id.*

592. *Id.* at 850.

593. *A.C. Aukerman*, 18 USPQ2D at 1623-24.

594. *Id.* at 1624.

595. *Id.*

596. *Id.* at 1625.

597. *Id.*

598. 952 F.2d 388, 21 USPQ2D 1281 (Fed. Cir. 1991).

599. *Id.* at 1283.

described a blood bag system similar to the commercial blood bag system produced by the patentee.⁶⁰⁰ At the time the prior art article had been published, the commercial blood bag system produced by the patentee contained a blood bag plasticized with DEHP. The prior art article did not, however, contain any express mention of DEHP.⁶⁰¹

The patentee had discovered the prior art article during preparation for an interference proceeding. Testimony taken during the interference proceeding was also submitted as part of the reexamination.⁶⁰²

The PTO Board concluded that, since the prior art article described the patentee's commercial system, and the patentee's commercial system utilized a DEHP plasticized blood bag, the skilled artisan would understand the prior art article as describing a blood bag plasticized with DEHP. Consequently, the Board found that the prior art article anticipated the claimed invention under 35 U.S.C. § 102(b).⁶⁰³

On appeal to the Federal Circuit, the dispositive question regarding anticipation was whether a skilled artisan would reasonably understand or infer from the prior art article that the blood bag described therein was plasticized with DEHP.⁶⁰⁴

The patentee argued that the testimony taken during the interference proceeding, upon which the Board had relied in affirming the § 102(b) rejection, was extrinsic evidence which should not have been considered in determining the anticipatory teachings of the prior art article.⁶⁰⁵ The Federal Circuit rejected this argument, holding that extrinsic evidence may be considered when it is used to explain, rather than to expand, the meaning of a reference.⁶⁰⁶ In the case of *In re Baxter Travenol*, the testimony taken during the interference was used to identify the material employed in the patentee's commercial blood bags, thereby explaining what the language in the prior art article would have meant to the skilled artisan.⁶⁰⁷ The testimony showed that the skilled artisan, reading the prior art article, would have understood the article to be

600. *Id.*

601. *Id.*

602. *Id.*

603. *Baxter*, 21 USPQ2D at 1284.

604. *Id.*

605. *Id.*

606. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576-77, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991).

607. *Baxter*, 21 USPQ2D at 1284.

describing a blood bag plasticized with DEHP.⁶⁰⁸

The patentee further argued that the skilled artisan would not necessarily have thought that the blood bag disclosed in the prior art article was plasticized with DEHP, since there were other, non-DEHP plasticizers available at the time the article had been published.⁶⁰⁹ The Federal Circuit found this argument unpersuasive, since the prior art article specifically described the patentee's commercial blood bag, and the patentee's commercial blood bag was known to be plasticized with DEHP.⁶¹⁰ Consequently, the Federal Circuit concluded that the prior art article disclosed all of the elements of the claimed invention, and this disclosure was unaffected by the availability of other, alternative elements.⁶¹¹

The Board's finding that the claims were anticipated by the prior art article was therefore affirmed by the Federal Circuit.⁶¹²

B. Claims Are Not Deemed Substantively Changed As a Matter of Law When Amended During Reexamination Following a Rejection Based on Prior Art

During reexamination of the subject patent in the case of *Lai-tram Corporation v. NEC Corporation*,⁶¹³ the examiner had rejected the patent claims under 35 U.S.C. § 102(b) and § 103 in view of certain newly cited references.⁶¹⁴ In response to the rejection, the patent owner had amended the claims and had pointed out how the teachings of the references differed from the amended claims.⁶¹⁵ The examiner allowed the claims, as amended.⁶¹⁶

In a subsequent suit for patent infringement, the alleged infringer asserted that because the amendment to the claims during reexamination had been made to overcome a rejection based on prior art, the amendment had been substantive as a matter of law.⁶¹⁷ Consequently, the patent owner could not recover damages for the alleged infringement during the period between the date of issuance of the original patent and the date of issuance of the reexamined patent, because the original and reexamined claims were not

608. *Id.*

609. *Id.*

610. *Id.*

611. *Id.*

612. *Baxter*, 21 USPQ2D at 1284.

613. 952 F.2d 1357, 21 USPQ2D 1276 (Fed. Cir. 1991).

614. *Id.* at 1277.

615. *Id.*

616. *Id.* at 1278.

617. *Id.*

"identical" in scope, as required by 35 U.S.C. § 252.⁶¹⁸

The patent owner responded by asserting that the amendment to the claims during reexamination had been done to more particularly define the invention, and that the words added by amendment stated inherent details and did not change the scope of the claims.⁶¹⁹

The district court did not decide the question of whether the changes to the claims were in fact substantive, or discuss the scope of the claims before and after amendment.⁶²⁰ The district court ruled summarily that any amendment to overcome a rejection on prior art is substantive as a matter of law.⁶²¹ The district court's grant of partial summary judgment in favor of the alleged infringer was certified for immediate appeal.

On appeal, the issue was whether amendments made to patent claims during reexamination of the patent are substantive as a matter of law, when the amendments are made following a rejection based on prior art.⁶²²

The Federal Circuit initially noted that the word "identical" in § 252 does not mean verbatim.⁶²³ Instead, the word "identical" in § 252 means, at most, without substantive change.⁶²⁴

The Federal Circuit noted further that the cases relied upon by the alleged infringer were cases in which prosecution history estoppel limited application of the doctrine of equivalents.⁶²⁵ The Federal Circuit observed that each of these cases had been decided on its particular facts, taking into account relevant evidence of the specification, prosecution history, prior art, and other pertinent circumstances.⁶²⁶ Consequently, none of these cases supported the *per se* rule urged by the alleged infringer.⁶²⁷

Thus, with respect to the issue of infringement under the doctrine of equivalents, Federal Circuit precedent had rejected the proposition that any amendment to a claim acts as a *per se* estop-

618. *Laitram*, 21 USPQ2D at 1279.

619. *Id.* at 1281.

620. *Id.* at 1280.

621. *Id.*

622. *Id.* at 1278.

623. *Laitram*, 21 USPQ2D at 1279.

624. *Seattle Box C. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 827-28, 221 USPQ 568, 575 (Fed. Cir. 1984).

625. *Laitram*, 21 USPQ2D at 1279.

626. *Id.*

627. *Id.*

pel.⁶²⁸ By analogy, in the case of *Laitram*, where the issue was substantive change on reexamination, the Federal Circuit similarly declined to adopt a rule of *per se* estoppel.

The Federal Circuit held that when claims are amended during reexamination following a rejection based on prior art, the claims are not deemed substantively changed as a matter of law. Instead, to determine whether a claim change is substantive, it is always necessary to analyze the claims of the original and the reexamined patents in light of the particular facts, including the prior art, the prosecution history, other claims, and any other pertinent information.

The Federal Circuit therefore reversed the grant of summary judgment and remanded the case for further proceedings.⁶²⁹

XVI. DISTRICT COURT JURISDICTION AND PROCEDURE

A. *The Proper Focus in Determining Subject Matter Jurisdiction Is Whether the Plaintiff Has Pleaded the Elements Required for a Patent Infringement Claim*

The Official Gazette of the PTO had listed the subject patent in the case of *Exxon Chemical Patents, Inc. v. Lubrizol Corporation*⁶³⁰ as being issued on September 19, 1989. On that same date the patentee had filed suit against the alleged infringer in district court.⁶³¹

However, for a substantial period of time after September 19, 1989 the patent document had not been printed, the patent grant had not been signed by or on behalf of the Commissioner, the official seal had not been affixed, a copy of the specification and claims had not been available to the public, and access to the prosecution history had been denied.⁶³²

Based upon these facts, the alleged infringer argued that the subject patent had not in fact issued on September 19, 1989 and that as of that date there had been no valid patent on which to sue. The alleged infringer therefore moved to dismiss the infringement suit for lack of subject matter jurisdiction.⁶³³

The district court denied the alleged infringer's motion to dismiss for lack of subject matter jurisdiction, and the alleged infringer

628. *Hi-Life Products, Inc. v. American National Water-Mattress Corp.*, 842 F.2d 323, 325, 6 USPQ2d 1132, 1134 (Fed. Cir. 1988).

629. *Laitram*, 21 USPQ2D at 1281.

630. 935 F.2d 1263, 19 USPQ2D 1061 (Fed. Cir. 1991).

631. *Id.* at 1061-62.

632. *Id.* at 1062.

633. *Id.*

appealed.⁶³⁴

On appeal, the Federal Circuit noted that jurisdiction of the district court is governed by 28 U.S.C. § 1338(a), which grants the district court original jurisdiction of any civil action "arising under any Act of Congress relating to patents." Jurisdiction under § 1338(a) exists when a well-pleaded complaint establishes that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law.⁶³⁵ Therefore, under the "well-pleaded complaint" rule, the proper focus in determining subject matter jurisdiction is on whether the plaintiff actually pleaded the elements required by the patent laws for a patent infringement claim.⁶³⁶

In *Exxon*, the Federal Circuit found that the patentee's complaint had pleaded a valid patent infringement claim. This "well-pleaded" complaint thereby established proper jurisdiction as a matter of law. The alleged infringer's challenge to jurisdiction was, in fact, directed only to the merits of a question of patent validity (including the date of patent validity). This question of patent validity remained to be resolved at trial. The Federal Circuit therefore held that the district court had correctly assumed jurisdiction under § 1338(a) on the basis of the well-pleaded complaint.⁶³⁷

B. A Post-filing Covenant Not to Sue May Be Considered In Evaluating Whether an Actual Controversy Exists

The patentee in the case of *Spectronics Corporation v. H.B. Fuller Company, Inc.*⁶³⁸ had sent a letter to various competitors, including the alleged infringer, announcing the issuance of the subject patent. After receiving the letter, the alleged infringer had filed suit against the patentee under the Declaratory Judgment Act, 28 U.S.C. § 2201, seeking a declaratory judgment that the patent was invalid or not infringed by the alleged infringer.⁶³⁹

After suit had been filed, the patentee entered into a covenant

634. *Id.* at 1062-63.

635. *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800, 808-09, 7 USPQ2d 1109, 1113 (1988).

636. *Kunkel v. Topmaster International, Inc.*, 906 F.2d 693, 695, 15 USPQ2d 1367, 1369 (Fed. Cir. 1990).

637. *Exxon*, 19 USPQ2D at 1063.

638. 940 F.2d 631, 19 USPQ2D 1545 (Fed. Cir. 1991).

639. The Declaratory Judgment Act, 28 U.S.C. § 2201(a), provides in pertinent part: "In a case of actual controversy within its jurisdiction, . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."

not to sue the alleged infringer for infringement of the patent claims. The patentee also submitted the patent to the PTO for reissue. The patentee then filed a motion to dismiss the alleged infringer's complaint for lack of jurisdiction under 28 U.S.C. § 2201 due to the absence of an "actual controversy." The district court granted the patentee's motion to dismiss, and the alleged infringer appealed.⁶⁴⁰

On appeal, the Federal Circuit initially observed that the existence of an "actual controversy" is an absolute requirement for proper jurisdiction under 28 U.S.C. § 2201.⁶⁴¹ In cases in which an alleged infringer seeks a declaratory judgment of patent invalidity or non-infringement, the courts apply a two-pronged test for determining whether an "actual controversy" exists. First, the accused infringer must have actually produced or prepared to produce an allegedly infringing product.⁶⁴² Second, the patentee's conduct must create an objectively reasonable apprehension on the part of the accused infringer that the patentee will initiate suit if the allegedly infringing activity continues.⁶⁴³

In the case of *Spectronics*, the alleged infringer argued that the required apprehension that the patentee will initiate suit should be determined at the time the complaint is filed, and that later events (such as a patentee's covenant not to sue) can not influence the jurisdiction of the district court under 28 U.S.C. § 2201.⁶⁴⁴

The Federal Circuit agreed that a party seeking a declaratory judgment must plead facts sufficient to establish the existence of an actual controversy at the time the complaint is filed, and that later events may not *create* jurisdiction where none existed at the time the complaint is filed. However, the Federal Circuit ruled that an actual controversy must be present at *all* stages of review, not merely at the time the complaint is filed, and that the burden is upon the alleged infringer to establish that an actual controversy existed at, and has continued since, the time the complaint was

640. *Id.* at 1547.

641. *Grain Processing Corp. v. American Maize-Products Co.*, 840 F.2d 902, 905, 5 USPQ2d 1788, 1791 (Fed. Cir. 1988).

642. *Jervis B. Webb Co. v. Southern Sys., Inc.*, 742 F.2d 1388, 1398-99, 222 USPQ 943, 949 (Fed. Cir. 1984).

643. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736, 6 USPQ2d 1685, 1689 (Fed. Cir. 1988); *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955, 3 USPQ2d 1310, 1311 (Fed. Cir. 1987); *Indium Corp. v. Semi-Alloys, Inc.*, 781 F.2d 879, 228 USPQ 845 (Fed. Cir. 1985), *cert. denied*, 479 U.S. 820, 93 L. Ed. 2d 37, 107 S. Ct. 84 (1986).

644. *Spectronics*, 19 USPQ2D at 1548.

filed.⁶⁴⁵

In the case of *Spectronics*, the covenant not to sue, forever prevented the patentee from asserting the patent claims against the alleged infringer, and the alleged infringer had thereby effectively "won" the non-infringement case pleaded in its complaint. The Federal Circuit concluded that the post-filing covenant not to sue was properly considered by the district court in evaluating whether an actual controversy existed.⁶⁴⁶

The alleged infringer further argued that, irrespective of the covenant not to sue, the potential grant of a reissue patent placed the alleged infringer at risk of further litigation on the subject matter contained in the patent.⁶⁴⁷

However, the Federal Circuit found no guarantee that the reissue patent would eventually issue. Moreover, even if the alleged infringer could establish an objectively reasonable apprehension that the patentee would initiate suit based upon the reissue patent, the alleged infringer could not demonstrate that its present activity was potentially infringing of any reissue patent claims, since no reissue patent claims yet existed by which infringement could be measured.⁶⁴⁸

The Federal Circuit therefore affirmed the judgment of the district court granting the patentee's motion to dismiss for lack of jurisdiction.⁶⁴⁹

C. A Grantee of All Substantial Patent Rights May Sue for Infringement In Its Own Name Without Joining the Patent Owner As a Party

The district court in the case of *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*⁶⁵⁰ found that the subject patent had been infringed. The infringer appealed, alleging that the suit should have been dismissed because the plaintiff was a mere patent licensee and could not maintain an infringement action without joining the patent owner as a party.⁶⁵¹

On appeal, the Federal Circuit noted that a patent license gives

645. *Amstar Corp. v. Envirotech Corp.*, 823 F.2d 1538, 1549, 3 USPQ2d 1412, 1420 (Fed. Cir. 1987); *International Medical Prosthetics Research Assocs. v. Gore Enter. Holdings, Inc.*, 787 F.2d 572, 575, 229 USPQ 278, 281 (Fed. Cir. 1986).

646. *Spectronics*, 19 USPQ2D at 1551.

647. *Id.* at 1549.

648. *Id.*

649. *Id.* at 1551.

650. 944 F.2d 870, 20 USPQ2D 1045 (Fed. Cir. 1991).

651. *Id.* at 1046.

the licensee no title in the patent and no right to bring suit in its own name for infringement.⁶⁵² If a licensee brings suit for infringement, then the licensee must join the patent owner as a party, so that the possibility of two separate suits on the same patent against a single infringer is eliminated.⁶⁵³

Whether a particular transfer of patent rights constitutes an assignment or a license is determined by the substance of the transaction, rather than by the name given to the transaction by the parties.⁶⁵⁴ If it appears from the agreement and the surrounding circumstances that the parties intended that the patent owner surrender all substantial rights to the invention, then the transfer will be considered an assignment.⁶⁵⁵

In the case of *Vaupel*, the patent owner had transferred to the plaintiff all but four rights to the invention.⁶⁵⁶ The Federal Circuit concluded that none of these four rights reserved by the patent owner was so substantial as to reduce the transfer to a mere license or indicate an intent not to transfer all substantial rights.⁶⁵⁷

One of the rights transferred by the patent owner to the plaintiff was the right to sue for infringement. Consequently, the Federal Circuit found that the suit provided complete relief between the plaintiff and the infringer, and there was no substantial risk that the infringer would incur double obligations to both the patent owner and the plaintiff. Therefore, the suit did not undermine the policy of eliminating the possibility of two suits on the same patent against a single infringer.⁶⁵⁸

The Federal Circuit therefore concluded that the agreement between the plaintiff and the patent owner, although not constituting a formal assignment, was a grant of all substantial rights and permitted the plaintiff to sue without joining the patent owner. The district court's ruling that the plaintiff had standing to sue for infringement without joining the patent owner as a party was there-

652. *Waterman v. Mackenzie*, 138 U.S. 252, 255, 34 L. Ed. 923, 11 S. Ct. 334 (1891).

653. *Crown Die & Tool Co. v. Nye Tool & Mach. Works*, 261 U.S. 24, 38, 67 L. Ed. 516, 43 S. Ct. 254 (1923).

654. *Waterman*, 138 U.S. at 256.

655. *Bell Intercontinental Corp. v. United States*, 381 F.2d 1004, 1011, 152 USPQ 182, 184 (1967).

656. The patent owner retained: 1) a veto right on sublicensing by the plaintiff; 2) the right to obtain patents on the invention in other countries; 3) a reversionary right to the patent in the event of bankruptcy or termination of production by the plaintiff; and 4) a right to receive infringement damages.

657. *Vaupel*, 20 USPQ2D at 1049.

658. *Id.*

fore affirmed.⁶⁵⁹

D. *A Member of the Public Who Perceives They Will Be Harmed By an Issued Patent Which They Believe to Be Invalid Does Not Necessarily Have Standing to Sue*

In the case of *Diamond v. Chakrabarty*,⁶⁶⁰ the U.S. Supreme Court held that non-naturally occurring man-made living microorganisms fall within the definition of patentable subject matter under 35 U.S.C. § 101.⁶⁶¹ In the case of *Ex Parte Allen*,⁶⁶² the PTO Board applied *Chakrabarty* to hold that § 101 was not a bar to patentability for a specific non-naturally occurring genetically altered strain of polyploid oysters.⁶⁶³

Shortly after the Board's decision in *Allen*, the PTO had issued a Rule which stated, in part, that the PTO "now considers non-naturally occurring, non-human multicellular organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. § 101."⁶⁶⁴

In the case of *Animal Legal Defense Fund v. Quigg*,⁶⁶⁵ various plaintiffs (including nonprofit organizations whose goal is the protection of animals) had filed suit in district court challenging the Rule on procedural and substantive grounds. The goal of these plaintiffs was to stop issuance of patents for animals.

The PTO Commissioner filed a motion to dismiss the complaint under Fed. R. Civ. P. 12(b)(6) for failure to state a claim. The motion was granted by the district court, and the plaintiffs appealed.⁶⁶⁶

In a first cause of action the plaintiffs had alleged that the Rule declaring animals to be patentability subject matter exceeded the

659. *Id.*

660. 447 U.S. 303, 65 L. Ed. 2d 144, 100 S. Ct. 2204 (1980).

661. § 101 Inventions patentable

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 101 (1988).

662. 2 USPQ2D 1425 (Bd. Pat. App. & Int. 1987), aff'd, 846 F.2d 77 (Fed. Cir. 1988).

See also *Ex Parte Hibberd*, 227 USPQ 443 (Bd. Pat. App. & Int. 1985).

663. *Chakrabarty*, 447 U.S. at 305.

664. See 1077 Official Gazette 24 (April 21, 1987).

665. 932 F.2d 920, 18 USPQ2D 1677 (Fed. Cir. 1991).

666. *Animal Legal Defense Fund v. Quigg*, 710 F. Supp. 728, 9 USPQ2D 1816 (N.D. Cal. 1989).

authority delegated to the Commissioner under the patent statute. As relief for this alleged violation, the plaintiffs sought a declaration that animals are not patentable subject matter under § 101 and an injunction against the issuance of any patents directed to animals.⁶⁶⁷

The plaintiffs had asserted essentially two types of personal injuries from the Commissioner's allegedly erroneous interpretation of § 101: (1) having to pay increased costs in the form of royalties on patented animals, and (2) suffering decreased profits because of competition from more productive non-naturally occurring animals.⁶⁶⁸

The Federal Circuit found that these alleged economic injuries were highly speculative and not "fairly traceable" to the Commissioner's allegedly erroneous interpretation of the statute.⁶⁶⁹ The Federal Circuit further found that the "zone of interests" of the patent laws is not so broad as to encompass any member of the public who perceives they will be harmed by an issued patent which they believe to be invalid. The Federal Circuit therefore concluded that the plaintiffs had failed to allege facts sufficient to give them standing to sue on the first cause of action.⁶⁷⁰

In a second cause of action the plaintiffs had asserted that the PTO Commissioner had violated the Administrative Procedure Act by failing to publish a notice of the proposed Rule in the Federal Register, by failing to allow interested persons an opportunity to submit public comment, and by failing to state the basis and purpose of the Rule following consideration of public comment.⁶⁷¹ The plaintiffs sought to enjoin the PTO from approving or issuing any patents on multicellular living organisms, including animals, or taking any action to effectuate the Rule, until the PTO complied with these procedural requirements.⁶⁷²

667. *Id.*

668. *Id.*

669. *Simon v. Eastern Kentucky Welfare Rights Org.*, 426 U.S. 26, 48 L. Ed. 2d 450, 96 S. Ct. 1917 (1976).

670. To establish standing to sue, a party must show (1) "that he personally has suffered some actual or threatened injury as a result of the putatively illegal conduct" (personal injury), (2) that "the injury 'fairly can be traced to the challenged action'" (causation), and (3) that the injury "is likely too be redressed by a favorable decision" (effective relief). *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 472, 70 L. Ed. 2d 700, 102 S. Ct. 752 (1982). In addition to these requirements for standing, the Supreme Court has further limited standing to those parties within the "zone of interests" a particular statute addresses. *Air Courier Conference of America v. American Postal Workers Union*, 112 L. Ed. 2d 1125, 111 S. Ct. 913, 59 U.S.L.W. 4140, 4142 (Feb. 26, 1991).

671. See 5 U.S.C. § 553(b) and (c).

672. *Animal Legal Defense Fund*, 18 USPQ2D at 1687.

On appeal, the Federal Circuit observed that prior public notice and comment regarding certain agency actions is required under § 553 of the Administrative Procedure Act.⁶⁷³ However, notice and public comment is not required for interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice.⁶⁷⁴

The Federal Circuit noted that the subject Rule clearly corresponded with the interpretation of § 101 set out in *Allen* and *Chakrabarty*. Thus, the Federal Circuit viewed the Rule as being merely interpretative of previous valid administrative actions and not representing a change in the law by the Commissioner. The Federal Circuit therefore concluded that the Commissioner's Rule fell within the "interpretative" exception to the § 553 public notice and comment requirement, and that the plaintiffs consequently had no standing to assert the second cause of action.

The Federal Circuit therefore affirmed the district court's ruling on the ground that the plaintiffs had lacked standing to sue.

E. Intervention Under Fed.R.Civ.P. 24(A)(2) Is Appropriate Only Where Disposition of the Action May Impair the Intervenor's Ability to Protect Its Interest

The subject patent in the case of *Chapman v. Manbeck*⁶⁷⁵ had lapsed because the patentee had failed to pay maintenance fees required under 35 U.S.C. § 41(b). The Commissioner had denied the patentee's petition to reinstate the lapsed patent pursuant to 35 U.S.C. § 41(c)(1). The patentee then filed an action under 5 U.S.C. § 701-06 in federal district court in Virginia to compel the Commissioner to reinstate the patent. The Virginia district court ordered the Commissioner to reinstate the patent.⁶⁷⁶

Previously, the patentee had filed suit against an accused infringer in federal district court in New Jersey. Immediately after the Virginia district court ordered the Commissioner to reinstate the patent, the patentee amended the complaint in the New Jersey suit to charge the accused infringer with infringement of the rein-

673. (b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments 5 U.S.C. § 553(b), (c).

674. 5 U.S.C. § 553(b)(A).

675. 931 F.2d 46, 18 USPQ2D 1565 (Fed. Cir. 1991).

676. *Id.* at 1566.

stated patent. The New Jersey district court thereafter issued an order preventing the accused infringer from raising a lapsed patent defense against the new infringement claim.⁶⁷⁷

The accused infringer then moved to intervene as a third party in the patentee's suit for reinstatement against the Commissioner in the Virginia district court. The Virginia district court denied the accused infringer's motion to intervene, and the accused infringer appealed that denial to the Federal Circuit.

On appeal, the Federal Circuit noted that intervention by third parties is governed by Rule 24 of the Federal Rules of Civil Procedure. Under subsection (a), Rule 24 permits intervention of right: "When the applicant claims an interest relating to the property or transaction which is the subject of the action and the applicant is so situated that the disposition of the action may *as a practical matter impair or impede* the applicant's ability to protect that interest, unless the applicant's interest is adequately represented by existing parties."⁶⁷⁸

The Federal Circuit found that the decision of the Virginia district court ordering reinstatement of the patent was not binding upon the New Jersey district court. If the New Jersey district court prevented the accused infringer from raising a lapsed patent defense, then the decision of the New Jersey district court could be challenged by the accused infringer via an appeal to the Federal Circuit. The Virginia district court action therefore did not impair the accused infringer's ability to fully litigate its rights. Consequently, the Virginia district court's denial of intervention did not "impair or impede" the accused infringer's interest "as a practical matter."⁶⁷⁹

The Federal Circuit therefore affirmed the Virginia district court's denial of the accused infringer's motion to intervene.

F. *Lear v. Adkins Does Not Override the Res Judicata Effect of a Consent Judgment Declaring a Patent Valid*

The subject patents in the case of *Foster v. Hallco Manufacturing Co., Inc.*⁶⁸⁰ had come into dispute between the same parties in an prior infringement litigation. The parties had entered a settlement agreement of that prior litigation, under which the alleged in-

677. *Id.*

678. Fed. R. Civ. P. 24(a)(2), [emphasis added].

679. The Federal Circuit additionally found that the Virginia district court had not abused its discretion in denying permissive intervention. *Chapman*, 18 USPQ2D at 1565.

680. 947 F.2d 469, 20 USPQ2D 1241 (Fed. Cir. 1991).

fringer had obtained a nonexclusive royalty bearing license under the patents. The parties had terminated the prior litigation by the entry of a consent judgment in which the alleged infringer had acknowledged the validity and infringement of the patents.⁶⁸¹

About four years after entry of the consent judgment, the alleged infringer began producing and marketing new models of the accused products. The alleged infringer took the position that the new accused products did not infringe the patents in the license agreement, and therefore the alleged infringer had no obligation to pay royalties to the patentee on sales of the new accused products. The patentee disagreed, taking the position that the new accused products were covered by the license agreement, and demanded royalty payments on the new accused products.⁶⁸²

The alleged infringer then filed suit, seeking a declaration that the patents were invalid and unenforceable. The patentee moved for partial summary judgment, on the ground that the alleged infringer was precluded from raising the issues of validity and enforceability by reason of the consent judgment entered in the prior litigation between the parties, which stated that the patents were valid and enforceable. The alleged infringer responded by asserting that the consent judgment was itself unenforceable because the consent judgment was equivalent to an agreement not to challenge the validity of a patent. The alleged infringer based its position on the case of *Lear v. Adkins*,⁶⁸³ in which the Supreme Court held that patent licensees are not precluded from challenging the validity of licensed patents because of the federal policy favoring full and free use of ideas in the public domain.

The district court held that the provision in the consent judgment with respect to the validity and enforceability of the patents contravened the federal patent policies recognized by the Supreme Court in *Lear v. Adkins* and, thus, the consent judgment did not preclude the alleged infringer from raising the issues of validity and enforceability.⁶⁸⁴

On appeal, the issue was whether the patent policy expressed in *Lear v. Adkins* overrides the res judicata⁶⁸⁵ effect which would

681. *Id.* at 1242.

682. *Id.*

683. 395 U.S. 653, 23 L. Ed. 2d 610, 89 S. Ct. 1902 (1969), 162 USPQ 1. *Foster*, 20 USPQ2D at 1244.

684. *Foster*, 20 USPQ2D at 1244.

685. Res judicata precludes the relitigation of a cause of action, or any possible defense to the cause of action, which is ended by a judgment of the court. Res judicata applies whether the judgment of the court is rendered after a trial and imposed by the court, or the

otherwise result from a consent judgment which declared a patent valid and enforceable.

The Federal Circuit observed that the issue considered by the Supreme Court in *Lear* involved the right of a patent licensee to challenge the validity of a licensed patent in a suit for royalties under a contract. The issue therefore involved a conflict between federal patent policy and state contract law. The Supreme Court in *Lear* concluded that federal patent policy should prevail, and therefore ruled in favor of precluding restrictions on attacks on patent validity.⁶⁸⁶

However, the Supreme Court in *Lear* did not deal with the specific fact situation presented in *Foster*, in which prior litigation had been terminated by a consent judgment that expressly acknowledged a patent's validity. In such a situation, the Federal Circuit found that other strong competing policy considerations came into play, namely, preserving the finality of judgments as well as the strong public policy of encouraging settlements. Moreover, unlike *Lear*, where there was a conflict between federal patent policy and state contract law, in *Foster* these strong competing policies did not involve questions of the primacy of federal law over state law.⁶⁸⁷

The Federal Circuit concluded that the patent policy expressed in *Lear v. Adkins* did not override the res judicata effect which would otherwise result from a consent judgment that declared a patent valid and enforceable.⁶⁸⁸ The Federal Circuit therefore reversed the district court's ruling based on *Lear* and held that a consent judgment respecting validity and enforceability may bar future litigation of those issues. However, because there were genuine issues of fact and law respecting the application of principles of res judicata, the Federal Circuit remanded to the district court for reconsideration of those issues.⁶⁸⁹

G. *Fed. R. Evid. 705 Is Applicable to Opinion Testimony on Infringement of Means-Plus-Function Claims*

The case of *Symbol Technologies, Inc. v. Opticon, Inc.*⁶⁹⁰ involved several patents directed to methods and devices employing

judgment is entered upon the consent of the parties in a consent judgment. *Foster*, 20 USPQ2D at 1244.

686. *Id.*

687. *Id.*

688. *Id.*

689. *Id.*

690. 935 F.2d 1569, 19 USPQ2D 1241 (Fed. Cir. 1991).

lasers to read bar codes.⁶⁹¹

At trial, the patentee had offered the testimony of an expert witness, accompanied by charts and drawings, to demonstrate infringement of the asserted claims, each of which contained "means plus function" limitations as permitted under 35 U.S.C. § 112, ¶6. The patentee's expert stated that, in his opinion, each claim limitation was met by a corresponding structure in the accused device.⁶⁹²

At trial, the patentee had suggested that, under Fed. R. Evid. 705,⁶⁹³ the district court receive the exhibits representing the expert's testimony without foundation, thereby avoiding the need to go through lengthy testimony explaining with each infringing device how the expert found that each element was infringed. The infringer raised no objection, and failed to cross-examine the patentee's expert on the issue.

The district court found infringement,⁶⁹⁴ and the infringer appealed the judgment. On appeal, the infringer argued that the patentee had failed to present sufficient evidence during its case-in-chief to establish a prima facie showing of infringement. The infringer contended that a party asserting infringement of claims containing "means plus function" limitations must demonstrate how each structure in the accused device, asserted to meet a functional claim limitation, is the same as or equivalent to a corresponding structure disclosed in the specification.⁶⁹⁵ The infringer argued that the patentee's expert had testified on the ultimate issue of infringement, but had failed to discuss in detail the equivalency between the structure of the accused device and the structure disclosed in the patent specification.⁶⁹⁶

The Federal Circuit observed, however, that the purpose of

691. *Id.* at 1242.

692. *Id.*

693. Rule 705 provides:

Disclosure of Facts or Data Underlying Expert Opinion

The expert may testify in terms of opinion or inference and give reasons therefor without prior disclosure of the underlying facts or data, unless the court requires otherwise. The expert may in any event be required to disclose the underlying facts or data on cross-examination.

Symbol Technologies, 19 USPQ at 1241.

694. *Symbol Technologies, Inc. v. Opticon, Inc.*, 17 USPQ2d 1737 (S.D.N.Y. 1990).

695. *See Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934, 4 USPQ2D 1737, 1739 (Fed. Cir. 1987), *cert. denied*, 485 U.S. 961, 108 S. Ct. 1226 (1988). In *Pennwalt* the Federal Circuit stated: "Where the issue is raised, it is part of the ultimate burden of proof of the patent owner to establish, with respect to a claim limitation in means-plus-function form, that the structure in the accused device which performs that function is the same as or an equivalent of the structure disclosed in the specification." *Id.*

696. *Symbol Technologies*, 19 USPQ2D at 1241.

Rule 705 is to abbreviate trials by permitting expert witnesses to state opinions without first specifying the data upon which the opinion is based. The Federal Circuit confirmed that Rule 705 is fully applicable to patent trials and to opinion testimony on infringement of claims under 35 U.S.C. § 112, ¶6.

The patentee was therefore permitted, under Rule 705, to rest its prima facie case on the expert's testimony that the patents were infringed. The Rule provided the infringer with the opportunity to demonstrate by cross examination that the expert's opinion testimony was factually incorrect. However, the infringer chose not to cross examine the patentee's expert on this issue. The Federal Circuit concluded that under Fed. R. Evid. 705 the patentee had made a prima facie showing of infringement and affirmed the judgment of the district court.⁶⁹⁷

H. *The Purpose of Requiring a Respondent to Post a Bond With the ITC Is to Protect the Complainant As Well As the Public Interest*

The complainant in the case of *Biocraft Laboratories, Inc. v. U.S. International Trade Commission*⁶⁹⁸ alleged that the respondent had violated § 337 of the Tariff Act of 1930⁶⁹⁹ by importing and selling crystalline cefadroxil monohydrate (cefadroxil), an antibiotic covered by the complainant's U.S. patent.⁷⁰⁰

The Commission had issued a temporary cease and desist order against the respondent. The temporary relief order had required the respondent to post a bond with the Commission to allow the respondent to sell cefadroxil which the respondent had imported prior to the temporary relief order. The temporary relief order stated that specific conduct otherwise prohibited by the order would be permissible if such specific conduct was authorized by the complainant in writing. Pursuant to the temporary relief order, the respondent posted a bond with the Commission.

The Commission subsequently concluded its § 337 investigation and issued a permanent cease and desist order against the respondent.⁷⁰¹ Shortly after the Commission issued the permanent relief order, the complainant and the respondent settled a separate district court litigation concerning the subject patent. The district

697. *Id.*

698. 947 F.2d 483, 20 USPQ2D 1446 (Fed. Cir. 1991).

699. 19 U.S.C. § 1337.

700. *Biocraft*, 20 USPQ2D at 1447.

701. *Id.*

court settlement agreement provided that the complainant would, if requested by the respondent, join in any petition by the respondent to obtain a return of the bond posted by the respondent with the ITC.⁷⁰²

The respondent then requested that the Commission return the bond. Pursuant to the district court settlement agreement, the complainant submitted a letter joining the respondent's petition. The Commission denied the respondent's request to return the bond, and the respondent appealed.⁷⁰³

On appeal, the respondent argued that the district court settlement agreement constituted the written authorization required by the temporary relief order, and thereby made the bonding requirement inapplicable. The respondent also pointed out that the purpose of the respondent's bond was to protect the complainant, and the complainant here had agreed to the Commission's return of the bond.⁷⁰⁴

The Commission, on the other hand, argued that the district court settlement between the respondent and the complainant had occurred after the respondent had made the sales covered by the bond, and that the temporary relief order required the complainant to provide written authorization prior to such sales being made.⁷⁰⁵

The Federal Circuit, agreeing with the respondent, found that once the sales in question had been authorized, the sales became exempt from the bond and were no longer a justification for the Commission to attempt to enforce the bond. The Federal Circuit observed that settlement of conflicts is in the public interest and should be encouraged. Where the complainant, whose competitive position was being protected by the bond, agreed to its return as part of a district court settlement agreement, return of the bond was consistent with the intent of the parties, thereby encouraging settlement. An opposite result would tend to discourage settlement.⁷⁰⁶

The Federal Circuit therefore held that where a complainant agrees as part of a settlement agreement to the return of a bond, the bond itself states that it does not apply to sales authorized by the complainant, and the purpose of the bond is to protect the complainant as well as the public interest, it is an abuse of discretion for the Commission to decline to return the bond merely because of

702. *Id.* at 1448.

703. *Id.*

704. *Id.* at 1449.

705. *Biocraft*, 20 USPQ2D at 1448.

706. *Id.* at 1449.

sales by a respondent of goods known to the complainant at the time of the settlement agreement. The Federal Circuit therefore reversed the Commission's denial of the respondent's request for return of the bond posted pursuant to the temporary relief order.⁷⁰⁷

XVII. APPELLATE COURT JURISDICTION AND PROCEDURE

A. *The Path of Appeal to the Federal Circuit Is Determined By the Basis of Jurisdiction in the District Court*

The case of *Abbott Laboratories v. Brennan*⁷⁰⁸ arose from an interference proceeding in the PTO involving a patent application of Brennan and a patent owned by Abbott. The Board had awarded priority of invention to Brennan.⁷⁰⁹

Abbott had then brought a civil action in district court pursuant to 35 U.S.C. § 146, seeking to set aside the award of priority to Brennan. Brennan had brought a counterclaim in the district court action for fraudulent misrepresentation, abuse of process, tortious interference with economic relations, antitrust violations, violation of the RICO Act, and intentional infliction of emotional distress.⁷¹⁰

The district court had awarded priority of invention to Brennan. The district court had also denied Brennan's motion for sanctions under Rule 11 and had denied Brennan's motion for a new trial on his counterclaim of tortious interference with economic relations. The district court had further denied Abbott's motion for JNOV or a new trial on the issue of abuse of process, and had partially denied Abbott's alternative motion for remittitur.⁷¹¹

Brennan and Abbott sought review by the Federal Circuit of various aspects of the judgment of the district court. However, Abbott did not seek review of the district court decision awarding priority of invention to Brennan.

The Federal Circuit observed that, in view of Abbott's omission of appeal on the issue of priority of invention, no issues arising under the patent law remained on appeal, and none had been referred to in the notice of appeal. The remaining issues on appeal were either matters of state law based on pendent jurisdiction, or issues of federal law that were not within the exclusive assignment of the Federal Circuit, but that had been properly included at

707. *Id.* at 1450.

708. 952 F.2d 1346, 21 USPQ2D 1192 (Fed. Cir. 1991).

709. *Id.* at 1193.

710. *Id.*

711. *Id.*

trial.⁷¹²

The threshold question was therefore whether the Federal Circuit had jurisdiction over the appeal.⁷¹³

The Federal Circuit noted that the path of appeal is determined by the basis of jurisdiction in the district court, and is not controlled by the district court's decision or the substance of the issues that are appealed.⁷¹⁴ Thus, the direction of appeal to the Federal Circuit does not change during or after trial, even when the only issues remaining are not within the exclusive assignment of the Federal Circuit.⁷¹⁵

Abbott's civil action had been properly brought under 35 U.S.C. § 146. The district court's jurisdiction had therefore arisen, in part, under the patent statute, Title 35, and thus satisfied the requirement of 28 U.S.C. § 1338(a).⁷¹⁶ All appeals in such circumstances are assigned exclusively to the Federal Circuit under 28 U.S.C. § 1295(a)(1).⁷¹⁷

The path of the appeal in *Abbott* had been established with the filing of the civil action to obtain a patent in accordance with 35 U.S.C. § 146. Although the § 146 issue was not appealed, the Federal Circuit concluded that the appeal of the other issues had been correctly taken to the Federal Circuit.⁷¹⁸

B. To Be Considered "Final", an Order Must Be Effectively Unreviewable on Appeal From a Final Judgment

During the pre-trial stages in the case of *Quantum Corporation v. Tandon Corporation*⁷¹⁹ the patentee had moved to compel the alleged infringer to produce documents relating to opinion letters of counsel. The alleged infringer had countermoved for a separate trial on the issue of willfulness after the conclusion of a trial on liability and damages, and for deferral of discovery of the attorney

712. *Id.*

713. *Abbott*, 21 USPQ2d at 1192.

714. *Id.*

715. See, e.g., *Technicon Instruments Corp. v. Alpkem Corp.*, 866 F.2d 417, 419-20, 9 USPQ2d 1540, 1541-42 (Fed. Cir. 1989); *Atari, Inc. v. JS&A Group, Inc.*, 747 F.2d 1422, 1427, 223 USPQ 1074, 1077 (Fed. Cir. 1984) (*en banc*).

716. 28 U.S.C. § 1338(a) provides that "The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents . . .".

717. 28 U.S.C. § 1295(a)(1) provides that "The United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction — (1) of an appeal from a final decision of a district court of the United States . . . if the jurisdiction of that court was based, in whole or in part, on section 1338 of this title . . .".

718. *Abbott*, 21 USPQ2d at 1192.

719. 940 F.2d 642 (Fed. Cir. 1991).

opinion letters until after the trial on liability and damages.⁷²⁰

The district court had granted the patentee's motion to compel production of the attorney opinion letters, and had denied the alleged infringer's motion to defer the trial on willfulness. The alleged infringer then sought to appeal the orders of the district court compelling production of the attorney opinion letters and deferring the trial on willfulness. The patentee moved to dismiss the appeal, arguing that the orders appealed from were not final and therefore were not appealable.⁷²¹

The Federal Circuit noted that before a district court order may be considered final, the order must (1) conclusively determine the disputed question, (2) resolve an important issue completely separate from the merits of the action, and (3) be effectively unreviewable on appeal from a final judgment.⁷²²

The Federal Circuit found that the two orders appealed from in *Quantum* did not satisfy the third requirement, because the two orders were effectively reviewable on appeal from a final judgment. Consequently, the Federal Circuit concluded that the two orders were not presently appealable, and granted the patentee's motion to dismiss.⁷²³

C. *The Sufficiency of the Evidence Underlying Presumed Jury Findings Cannot Be Challenged on Appeal Where a Motion for a Directed Verdict Was Not Made at the Close of the Evidence*

The case of *Jurgens v. McKasy*⁷²⁴ involved an appeal from a district court judgment in a jury case involving patent infringement. The judgment awarded damages and injunctive relief to the patent owner for infringement of a patent directed to a windsock device.⁷²⁵

In *Jurgens*, the infringer had failed to bring a motion for a directed verdict at the close of the evidence. Where a motion for a directed verdict is not made at the close of the evidence, the sufficiency of the evidence underlying presumed jury findings cannot be

720. *Id.* at 643.

721. *Id.*

722. *Id.* See also, *Gulfstream Aerospace Corp. v. Mayacamas Corp.*, 485 U.S. 271, 276, 99 L. Ed. 2d 296, 108 S. Ct. 1133 (1988); *Cohen v. Beneficial Industrial Loan Corp.*, 337 U.S. 541, 546, 93 L. Ed. 1528, 69 S. Ct. 1221 (1949).

723. *Quantum*, 940 F.2d at 642.

724. 927 F.2d 1552, 18 USPQ2D 1031 (Fed. Cir. 1991).

725. *Id.*

challenged on appeal.⁷²⁶ Accordingly, when the infringer failed to move for a directed verdict at the close of the evidence, the infringer waived its right to challenge the presumed jury findings as unsupported by substantial evidence. That failure dramatically changed the standard of review on appeal with respect to fact issues decided by the jury.⁷²⁷

For example, on appeal the infringer challenged the district court's finding of patent validity under 35 U.S.C. § 103 in view of two prior art references. Before the district court the patent owner had argued that the first of these two prior art references was not analogous art, and that the second of these two prior art references did not show a windsock.⁷²⁸

The question of what constitutes analogous art, as well as the question of what a reference teaches, are questions of fact for the jury to decide. On appeal, it is presumed that the jury decided these fact questions in favor of the patent owner, concluding that the first reference was not analogous art and that the second reference did not show a windsock.⁷²⁹

Because the infringer had failed to move for a directed verdict, the infringer could not challenge these presumptions on appeal. Consequently, the Federal Circuit was required to presume that the first reference was not analogous art and that the second reference did not disclose a windsock. In accordance with these presumptions, the Federal Circuit concluded that the first reference could have no bearing on the validity of the patent under 35 U.S.C. § 103, and that the second reference would not have rendered the patent invalid under 35 U.S.C. § 103.⁷³⁰

On appeal, the infringer also challenged the district court's finding of patent infringement under the doctrine of equivalents. The infringer asserted that if infringement was present under the doctrine of equivalents, then the patent would encompass the prior art.⁷³¹ More specifically, to cover the infringing windsocks literally, the hypothetical claim would define a windsock which would have been obvious in view of the second reference.

However, for the reasons stated above, the Federal Circuit was

726. *Smith v. Ferrel*, 852 F.2d 1074, 1075 (8th Cir. 1988); *Hubbard v. White*, 755 F.2d 692, 695-96 (8th Cir.), *cert. denied*, 474 U.S. 834, 88 L. Ed. 2d 87, 106 S. Ct. 107 (1985).

727. *Jurgens*, 18 USPQ2D at 1031.

728. *Id.*

729. *Id.*

730. *Id.*

731. *Wilson Sporting Goods Co. v. David Geoffrey & Assoc.*, 904 F.2d 677, 683, 14 USPQ2D 1942, 1947-48 (Fed. Cir. 1990).

required to presume that the second reference did not disclose a windsock. In accordance with this presumption, the Federal Circuit concluded that the hypothetical claim, viewed as a whole, would not have been obvious in view of the second reference and that the second reference therefore did not bar infringement by equivalents. The judgment of the district court was therefore affirmed.

D. *A Post-verdict Motion Is a Prerequisite to Appellate Review of the Sufficiency of the Evidence Underlying a Jury Verdict*

At the conclusion of testimony in the case of *Biodex Corporation v. Loredan Biomedical, Inc.*,⁷³² the patentee had orally moved for a directed verdict. The patentee had not made a specific assertion that the alleged infringer's evidence in support of invalidity or non-infringement had been insufficient, although judgment had been requested on both issues as a matter of law. The district court never ruled upon the patentee's motion.⁷³³

Both parties had requested and submitted various jury instructions. The district court, however, drafted its own instructions, to which the patentee had objected.

The district court submitted the case to the jury with multiple special verdict forms. In the special verdicts, the jury found that one patent had been proven invalid and that the other patent had not been infringed. The district court entered judgment on the jury verdicts. The patentee made no post-verdict motions, either by renewing its motion for a directed verdict, moving for a new trial, or by moving for judgment non obstante veredicto ("JNOV"). The patentee appealed the judgment of the district court.⁷³⁴

On appeal, the patentee argued that neither special verdict had been supported by substantial evidence.

The Federal Circuit viewed the issue on appeal as being whether a post-verdict motion is a prerequisite to appellate review of the sufficiency of the evidence underlying a jury verdict. In *Biodex*, the patentee had made an oral motion for a directed verdict at the conclusion of the evidence. However, the patentee had not re-submitted or renewed the motion in any form after the verdict.

The Federal Circuit reasoned that a requirement for an express post-verdict motion by the potential appellant assists appellate re-

732. 946 F.2d 850, 20 USPQ2D 1252 (Fed. Cir. 1991).

733. *Id.* at 1253.

734. *Id.*

view. A rule that requires explicit formulation and specification of the preserved issues after the verdict requires the prospective appellant to present the preserved issues to the district court in a well-known and defined format after the verdict.⁷³⁵

The Federal Circuit therefore concluded that it could not review the sufficiency of the evidence after a jury verdict absent some post-verdict motion. The patentee's failure to present the district court with a post-verdict motion precluded appellate review of the sufficiency of the evidence, and was thereby dispositive of that portion of the appeal directed to whether there was substantial evidence to support the special verdicts.⁷³⁶

On appeal, the patentee also contended that the district court's failure to give the patentee's requested jury instructions was prejudicial error.⁷³⁷ The Federal Circuit noted that jury instructions must be both legally correct and sufficiently comprehensive to address factual issues for which there is disputed evidence of record. To succeed on appeal, the patentee must (1) prove that the jury instructions, read in their entirety, were incorrect or incomplete as given, and (2) demonstrate that the jury instructions suggested by the patentee could have cured the error. The Federal Circuit concluded that the patentee had failed in both tasks.⁷³⁸

Since the Federal Circuit concluded that it may not review for sufficiency of the evidence, and since there was no prejudicial legal error, the Federal Circuit affirmed the judgment of the district court.

E. *Prejudicial Legal Error Must Be Shown to Vacate a Judgment Where No Motion for JNOV or a New Trial Was Made After a Jury Verdict*

Before the district court, the appellants in the case of *Acoustical Design, Inc. v. Control Electronics Company, Inc.*⁷³⁹ had failed to move for a directed verdict after the close of testimony, had failed to move for judgment notwithstanding the verdict (JNOV), and had failed to move for a new trial. The district court entered final judgment holding the appellants liable for patent infringement and enjoining them from further infringement.

On appeal, the issue was whether the Federal Circuit should

735. *Id.*

736. *Id.*

737. *Biodex*, 20 USPQ2D at 1252.

738. *Id.*

739. 932 F.2d 939, 18 USPQ2D 1707 (Fed. Cir. 1991).

vacate and remand for a new trial a judgment rendered on a jury verdict when no motions for directed verdict, JNOV, or new trial were made before the district court.

Rule 50(b) of the Federal Rules of Civil Procedure permits a motion for JNOV only when a party has previously moved for a directed verdict. If no motions for JNOV or new trial are made in the district court after a jury verdict, then the appellant is required to show that prejudicial legal error occurred in the conduct of the trial in order for the Federal Circuit to vacate the judgment of the district court and remand for a new trial.⁷⁴⁰

The Federal Circuit concluded that the appellants had not demonstrated that prejudicial legal error occurred in the conduct of the trial. Consequently, the Federal Circuit affirmed the judgment of the district court.

F. Sanctions May Be Appropriate Where an Appeal Is "Frivolous as Filed" or "Frivolous as Argued"

The appeal in the case of *Finch v. Hughes Aircraft Company*⁷⁴¹ resulted from a history of over twelve years of litigation by the appellant against the appellee.

The appellant and the appellee had originally been co-defendants in a federal district court action in which the appellant had filed a cross-claim against the appellee. After filing the cross-claim, the appellant filed a separate complaint, in the same district court, asserting claims identical to those in the cross-claim. All of the counts alleged in both the complaint and the cross-claim were disposed of by summary judgment for the appellee.

The appellant then filed a separate complaint against the appellee in the same district court, substantially identical to the cross-claim. The appellee moved for a dismissal of the complaint, and the appellant did not oppose the motion. The district court granted the appellee's unopposed motion to dismiss the new complaint, holding that the complaint was duplicative of the proffered cross-claim and that each count of the new complaint was barred by res judicata.

On appeal, the Federal Circuit affirmed the district court's order dismissing the complaint because the appellant had failed to oppose the motion to dismiss, because the complaint was duplicative, and because each claim in the complaint was barred by res judicata.

740. *Railroad Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1511, 220 USPQ 929, 934 (Fed. Cir. 1983), cert. denied, 469 U.S. 871, 105 S. Ct. 220, 83 L. Ed. 2d 150, 224 USPQ 520 (1984).

741. 926 F.2d 1574, 17 USPQ2D 1914 (Fed. Cir. 1991).

Having determined that the district court's judgment must be affirmed, the Federal Circuit then addressed the appellee's request for sanctions.

The Federal Circuit noted that there are two distinct bases on which an appeal may be deemed frivolous, either one of which alone is sufficient to support sanctions. First, an appeal may be deemed "frivolous as filed" if the judgment of the district court is so plainly correct and the legal authority contrary to the appellant's position is so clear that there is no appealable issue.⁷⁴² Second, an appeal may be deemed "frivolous as argued" where genuinely appealable issues may exist, but the appellant's contentions in prosecuting the appeal are frivolous.⁷⁴³

In the case of *Finch*, the Federal Circuit found the appellant's appeal to be both frivolous as filed and frivolous as argued. Because the appellant had no arguable basis in fact or in law for filing the appeal and had made numerous arguments in support of the appeal that were without any basis, the Federal Circuit granted the appellee's request for sanctions under Rule 38 of the Federal Rules of Appellate Procedure and required the appellant to pay the appellee double its costs.

742. See, e.g., *In re Perry*, 918 F.2d 931, 935 (Fed. Cir. 1990); *Octocom Systems, Inc. v. Houston Computer Servs., Inc.*, 918 F.2d 937, 943, 16 USPQ2D 1783 (Fed. Cir. 1990); *Synan v. Merit Systems Protection Bd.*, 765 F.2d 1099, 1102 (Fed. Cir. 1985).

743. *Refac Int'l, Ltd. v. Hitachi, Ltd.*, 921 F.2d 1247, 1256, 16 USPQ2D 1347, 1354 (Fed. Cir. 1990); *Laitram Corp. v. Cambridge Wire Cloth Co.*, 919 F.2d 1579, 1583, 16 USPQ2D 1929, 1933 (Fed. Cir. 1990); *Devices for Medicine, Inc. v. Boehl*, 822 F.2d 1062, 1068-69, 3 USPQ2D 1288, 1294 (Fed. Cir. 1987).

DEVELOPING CRITICAL TECHNOLOGIES: A LEGAL AND POLICY ANALYSIS

Lewis D. Solomon*
and
Suzanne E. Schoch**

I. INTRODUCTION

The concept of critical technologies in the United States first emerged as a way to guard scientific knowledge about technology to protect national security.¹ The National Defense Authorization Act for Fiscal Year 1989² included requirements for a critical technologies plan to develop the technologies most essential to ensure superiority of United States weapons systems.³ Since then, the critical technologies concept has expanded. Ensuring national security includes not only defense leadership but also commercial prosperity. Advancement of critical technologies creates new industries and generates jobs leading to increased economic growth and improved global competitiveness of the United States.

Technological advancement requires basic research undertaken to gain knowledge and understanding of the fundamental aspects of the universe. The difficulty of investing in basic research for private industry is threefold: it is long-term; the results are not always marketable; and the rewards may not be evident.⁴

Applied research and development are also crucial for technological advancement. A goal of applied research is "to provide technological solutions to identified problems."⁵ "Development is the

Copyright © 1993 by Lewis D. Solomon and Suzanne E. Schoch.

* Mr. Solomon is a Arthur Selwyn Miller Research Professor of Law at the George Washington University National Law Center.

** Ms. Schoch holds a B.A. from the University of Richmond and a J.D. from the George Washington University National Law Center.

1. The Initial Military Critical Technologies List, 45 Fed. Reg. 65,014 (1980), merely listed exports believed to threaten national security. Kenneth Propp, Note, *Export Controls: Restrictions on the Export of Critical Technologies*, 22 HARV. INT'L L.J. 411, 411 (1981).

2. National Defense Authorization Act, Fiscal Year 1989, Pub. L. No. 100-456, 102 Stat. 1918 (1988).

3. *Id.* 102 Stat. at 2018 (codified as amended at 10 U.S.C. § 2368 (1988)).

4. Wendy H. Schacht, *Technological Advancement and U.S. Industrial Competitiveness*, CONG. RES. SERVICE REP., Oct. 28, 1988, at 5.

5. *Id.*

process of taking the results of research and using them to generate . . . commercially viable technologi[es]."⁶ The last stage of technological development is the commercialization of the new products and processes. It is here that U.S. companies need to succeed, where technology arguably has the " 'greatest economic impacts in terms of productivity, growth, and competitiveness.' "⁷

This article focuses on the commercialization of innovative critical technology. It examines U.S. technology policy including research and development (R&D) funding, macroeconomic influences and recent federal initiatives. In looking to the future, the free market advocates, private sector competitiveness groups, and government agencies will all vie for the lead role in directing the technology competitiveness of the United States.

II. U.S. TECHNOLOGY POLICY

"The goal of U.S. technology policy is to make the best use of technology in achieving the national goals of improved quality of life for all Americans, continued economic growth, and national security."⁸ U.S. policy excludes U.S. technology pre-eminence as part of its goals. In implementing this policy, the Federal Government maintains that all parts of the economy, including federal, state, and local governments, industry and academia have roles to play.⁹ In addition, U.S. technology policy provides that the U.S. system of free enterprise should not be tampered with, nor should U.S. policy favor one industry over another.¹⁰ Yet, the federal government wields power that interferes with free enterprise.

The U.S. government spends large amounts of money funding research and development. Such funding aids those private businesses that are able to commercialize this basic research. Macroeconomic policy such as tax policy indirectly influences the success of certain industries. Similarly, the lack of coordination of a technology policy among the various departments and agencies of government has an indirect effect on technological advancement in the private sector.

In the post-World War II era, the framework for the U.S. government's support for science and technology can be traced to Van-

6. *Id.*

7. *Id.* at 6 (citing John M. Marcum, *Technology Leadership: Co-operation, Competition, and Interdependency*, SCI. AND PUB. POL'Y, Dec. 1985, at 319).

8. OFFICE OF SCIENCE AND TECHNOLOGY POLICY, EXECUTIVE OFFICE OF THE PRESIDENT, U.S. TECHNOLOGY POLICY 2 (1990).

9. *Id.*

10. *Id.* at 1-2.

nevar Bush's report "Science, the Endless Frontier."¹¹ The report argued that science could yield an infinite stream of benefits to society.¹² The report concluded that support for science and technology is an appropriate role for the government, but that the applied or developmental aspect should be left to private industry.¹³

Traditionally, U.S. government support of science and technology focused on basic research and the application and development of technology to meet the needs of specific national missions, such as defense, health, and space exploration.¹⁴ The thrust for federally funding basic research is premised on the assumption that private industry will underinvest in basic research because of industry's inability to capture all of its benefits.¹⁵ Due to basic research's significant long term potential benefits to the economy and society, policymakers have deemed it necessary and proper for the government to strongly support and federally fund basic research.¹⁶

Industries have relied on revolutionary breakthroughs and innovations based upon discoveries and advances derived from basic research. The typical innovation process in the U.S. has begun with a major scientific breakthrough, progressed through design, development and production, and ended with marketplace distribution.¹⁷ The U.S. excelled in this method of innovation and achieved preeminence in science and technology in the post-World War II era.¹⁸

In the 1980s, a shift occurred in three aspects of the United States' science and technology policy. First, changes occurred in the organization and funding of civilian research programs in an attempt to "improve the ability of U.S. firms to realize the commercial profits from the innovations spawned by such research."¹⁹ Second, defense research funding began to be used "to support advances in civilian technologies in order to [promote] eventual technological improvements for the military."²⁰ Third, "the new

11. VANNENAR BUSH, SCIENCE, THE ENDLESS FRONTIER: A REPORT TO THE PRESIDENT ON A PROGRAM FOR POSTWAR SCIENTIFIC RESEARCH (1945).

12. See *id.* at 5, 10-11.

13. *Id.* at 22.

14. COUNCIL ON COMPETITIVENESS, GAINING NEW GROUND: TECHNOLOGY PRIORITIES FOR AMERICA'S FUTURE 13 (1991).

15. *Id.*

16. *Id.*

17. COUNCIL ON COMPETITIVENESS, PICKING UP THE PACE: THE COMMERCIAL CHALLENGE TO AMERICAN INNOVATION 10 (1988).

18. *Id.*

19. David C. Mowery & Nathan Rosenberg, *New Developments in U.S. Technology Policy: Implications for Competitiveness and International Trade Policy*, CAL. MGMT. REV., Fall 1989, at 107, 107.

20. *Id.*

science and technology policy priorities of the U.S. government and the increased salience of these issues for foreign governments have elevated the importance of science and technology issues within trade policy."²¹ Some fear that these shifts could have a "chilling effect on the international scientific and engineering cooperation and communication," and that policies are being proposed "with little apparent recognition of their implications for other foreign and domestic policy goals."²²

At the present time, the U.S. government does not have a formal delineated national policy for innovation and high technology development. The United States appears to be the only major industrialized country that does not have a national policy in this area, although the federal government does have certain technology programs. An ad hoc, uncoordinated approach may be unwise, however, since the relationship between government and industry is one of the most significant factors affecting innovation and the environment where technological development occurs. The absence of cooperation can be detrimental to the long-term economic health of the U.S. as it faces increasing competition from foreign companies where close government-industry collaboration is the norm, not the exception.²³

A. *Federal Funding of Research and Development (R&D)*

Federal funding of R&D is extremely critical for U.S. economic stability and strength because the commercial marketplace has failed to channel enough resources into R&D. The U.S. high technology industries have tended to underinvest in R&D because they cannot capture all the benefits from their investments. Most private industry R&D goes to projects that are highly likely to bring short term success, while the long term research projects are neglected although they may be worth more to the nation as a whole. Therefore federal funding needs not only to increase its aggregate level of spending, but also shift it toward long term projects in which social returns may exceed private ones.²⁴

Government funding of R&D can be broken down into two main components: defense and non-defense. In 1980, "[f]ederal

21. *Id.*

22. *Id.*

23. Wendy H. Schacht, *Industrial Innovation: Debate Over Government Policy*, CONG. REP. SERVICE ISSUE BRIEF, August 2, 1991, at 4-5.

24. UNITED STATES CONGRESS BUDGET OFFICE, *FEDERAL FINANCIAL SUPPORT FOR HIGH TECHNOLOGY INDUSTRIES 2* (1985).

R&D spending was evenly divided between defense and non-defense."²⁵ By 1990, federal defense R&D expenditures reached 61% of federal R&D spending, while non-defense R&D expenditures plummeted to 39%.²⁶ Comparing federal R&D funding of defense and civilian sectors provides a stark contrast. Of civilian R&D funding in 1990, basic research comprised 45%, development 27% and applied research 29%. Of defense R&D funding in 1990, 2% was used for basic research, 90% for development, and 8% for applied research.²⁷

A significant distinction now exists between defense and non-defense R&D. In the past, defense related R&D has benefitted U.S. private sector commercial technological capabilities.²⁸ Research derived from defense-related R&D could be "spun off" to create commercially marketable products.²⁹ Examples of defense related spinoffs include commercial jet airplanes and computers.

Current evidence shows that spinoffs associated with defense-related R&D are no longer widespread.³⁰ The research necessary to develop defense equipment differs widely from the research needed for civilian products.³¹ For example, the research involved in the development of the B-2 Stealth bomber is not compatible with the needs of Boeing in developing a new jet or improving an old jet.

Furthermore, the evidence indicates that the commercial sector will drive future strategic technologies.³² Today's leading-edge technology in microelectronics, computers, and telecommunications is found in the private sector.³³ Yet, federal R&D spending continues to favor defense R&D expenditures over the increasingly more important non-defense R&D expenditures.³⁴

One federal agency that has engaged in both defense and non-defense oriented R&D is the Defense Advanced Research Projects Agency or DARPA.³⁵ Originally named ARPA, it was created as a

25. Michael E. Davey, *Science and the Budget: 1990 Update*, CONG. RES. SERVICE REV., July-August 1990, at 37, 37.

26. COUNCIL ON COMPETITIVENESS, *supra* note 14, at 15.

27. Michael E. Davey, *Research and Development Funding: FY1990*, CONG. RES. SERVICE ISSUE BRIEF, Jan. 2, 1990.

28. Davey, *supra* note 25, at 37.

29. *Id.*

30. *Id.*

31. *Id.*

32. COUNCIL ON COMPETITIVENESS, *supra* note 14, at 20.

33. *Id.*

34. See *supra* note 26 and accompanying text.

35. Marc S. Miller, *The Government's Guiding Hand*, TECH. REV., Feb.-March 1991, at 35, 35.

small office in the Pentagon in response to the Soviet launching of Sputnik.³⁶ After the National Air and Space Administration (NASA) took over the space program, DARPA became the "technology mission agency" involved in R&D since it gave out military contracts in civilian science and engineering.³⁷

This small, "little-known band of maverick scientists and engineers" are officially charged with preventing technology surprises from abroad and dealing with them when they occur.³⁸ They do this by "advancing seed money and nurturing promising research at universities, national laboratories and leading edge industries."³⁹ By funding the exploration of the outer limits of technology, DARPA has been credited with the creation of the field of computer science in the United States.⁴⁰

DARPA acts independently from the armed services R&D communities and apart from the national laboratories, thereby eliminating the bureaucratic layers.⁴¹ It has not confined itself to acting within the dominating paradigm of minimal government involvement in commercial technologies, but instead has focused on the technologies, whether military or commercial, that it has seen as necessary for the future competitiveness of the United States. DARPA has operated on the assumption that national defense means both developing new weapons and supporting basic research in commercial technologies.⁴² This became easier when Congress, in November of 1989 expanded DARPA's authority to allow it to provide venture capital to private companies.⁴³

DARPA quickly became active using its new authority to support research in areas such as high-definition television (HDTV), superconductivity, and artificial intelligence.⁴⁴ As the free market debate intensified, the proponents of government intervention sought to use DARPA to guide national high technology industries. This has made DARPA the "lightning rod" in the storm of "debate about the role of long-term defense research in an era of lessening

36. *Id.*

37. *Id.*

38. James Kitfield, *Walking a High-Tech Tightrope*, GOV'T EXECUTIVE, May 1990, at 22, 22.

39. *Id.* at 23.

40. John Markoff, *Making Industrial Policy at the Pentagon*, N.Y. TIMES, Nov. 19, 1989, at § 4, 4.

41. *Id.*

42. *Id.*

43. *Industrial Policy; Beheaded*, THE ECONOMIST NEWSPAPER, April 28, 1990, at 27, 27.

44. *Id.*

military tensions” and “the future of U.S. high tech[nology] competitiveness.”⁴⁵ DARPA’s “industrial policy” has been extremely successful at doing what the free market purists said would not work; it was meddling in the private sector as a high tech venture capitalist and getting results. With the controversial firing of the Director of DARPA, Craig Fields, an industrial policy advocate, in May of 1990, outsiders think the agency will return to funding specific military projects.⁴⁶

Although the United States spends more in absolute terms on R&D, U.S. non-defense R&D, which is more important than defense R&D for economic competitiveness, has failed to keep pace with that of other industrialized countries.⁴⁷ For example, Japan spends approximately 50% more on non-defense R&D as a percentage of Gross Domestic Product (GDP) than the United States.⁴⁸ Furthermore, the United States non-defense R&D expenditures are growing at a slower pace in comparison to Japan and other industrialized countries.⁴⁹ While the other countries have increased their non-defense expenditures by approximately 50% since 1972, the United States has only slightly increased the percentage of Gross National Product (GNP) spent on non-defense R&D.⁵⁰

Also, as a percentage of total federal and private spending in non-defense R&D, federal spending has dropped sharply in recent decades.⁵¹ From 1970 to 1990, federal funding dropped from 31% of total U.S. public sector expenditures in non-defense R&D to only 17% of the total.⁵²

The United States spends a large portion of its non-defense R&D budget on “big science” projects such as the space station, the superconducting super collider⁵³ and the Strategic Defense Initiative (Star Wars). Major increases in funding for these “big science” projects continue to be sought at the expense of other smaller projects that could develop commercially applicable technology.⁵⁴ In 1990, estimates indicated that in the coming decade, all “big science” projects planned by the federal government will require over

45. Kitfield, *supra* note 38, at 23.

46. Evelyn Richards, *Uncle Sam as a Venture Capitalist*, WASH. POST, April 29, 1990, at H1, H5.

47. COUNCIL ON COMPETITIVENESS, *supra* note 14, at 15.

48. *Id.*

49. *Id.*

50. *Id.*

51. *Id.*

52. COUNCIL ON COMPETITIVENESS, *supra* note 14, at 15.

53. Davey, *supra* note 25, at 38.

54. *See id.*

\$60 billion to complete and another \$100 billion to operate and maintain.⁵⁵ Critics of these projects assert that the financial commitment required to complete these "big science" projects will seriously jeopardize federal R&D spending in the future, thereby limiting the country's ability to respond to future technological challenges.⁵⁶

In the post-World War II era, policy makers proceeded on the assumption that funding basic scientific research adequately provides a foundation for technological development and commercialization. Unfortunately, basic research, without more, often is insufficient in leading commercially viable technology. According to the National Science Foundation (NSF), the U.S. targets less than 1% of federal R&D funding at improving our commercial development capabilities.⁵⁷ In contrast, Japan spends 4.8% of government R&D funds to advance its commercial capabilities.⁵⁸

In Congressional appropriations for fiscal year 1991, the DoD funding level for R&D decreased from \$36.7 billion to \$36 billion although an increase of \$1.4 billion was requested.⁵⁹ The unwillingness of the U.S. to fund more non-defense R&D, generally, and developmental research, specifically, may lie at the heart of why the U.S. has lost much of its technologic and economic preeminence in the past several decades.

B. *U.S. Macroeconomic Policy and Government Structure*

Governmental organization and procedures have a significant impact on the effective development of commercially viable technology.⁶⁰ Lack of coordination and inability to implement policies can undermine the best technology policies.⁶¹ No one federal agency exists that has broad responsibility for the research and other necessary activities related to the private sector technology or for the

55. *Id.*

56. *Id.*

57. *Id.*

58. Davey, *supra* note 25, at 38; *see also*, COUNCIL ON COMPETITIVENESS, *supra* note 14, at 13.

59. *See* Michael E. Davey, *Research and Development Funding: FY1991*, CONG. RES. SERVICE ISSUE BRIEF, Jan. 14, 1991, at 7. DARPA's funding however, was increased 14% to \$1.4 billion in FY '91. *Id.* at 6. Within the DOC, the NIST R&D budget increased from \$164 million in FY '90 to \$215 million in FY '91. *Id.* at 15. Within the 1991 funding, \$35.9 million was appropriated for the ATP and \$11.9 million for the Centers for Transfer of Manufacturing Technology. *Id.* at 13.

60. COUNCIL ON COMPETITIVENESS, *supra* note 17, at 26.

61. *Id.*

strategic coordination of technology policy at the national level.⁶²

Only the White House Office of Science and Technology Policy (the Office) provides an overview of R&D and other activities related to economic performance.⁶³ However, the Office functions primarily as an advisory body to the President.⁶⁴ The Office has a small budget and its staff consists primarily of personnel on temporary loan from other agencies.⁶⁵

The Department of Commerce (DoC) operates the only federal laboratory explicitly charged with serving the needs of U.S. industry;⁶⁶ [it was originally named the National Bureau of Standards, and is now called the National Institute of Standards and Technology (NIST)]. The small office of Productivity, Technology and Innovation within NIST works to create a climate favorable for innovation and technology, and its National Technical Information Service serves as a resource for the private sector to receive scientific and technical information.⁶⁷ The NIST also administers the Advanced Technology Program (ATP).⁶⁸ The purpose of the ATP is to assist U.S. businesses in creating and applying generic technology and research results.⁶⁹ The money is provided in the form of matching funds for small companies or consortiums.⁷⁰ Yet this effort to fund the cutting edge technologies has only been appropriated \$10 million in fiscal year 1991, although the budget is likely to increase if the Program maintains its role of development of generic technologies through the pre-competitive phase.⁷¹

The National Science Foundation (NSF) has the responsibility to support education, transfer research and information, as well as to serve as the general science and engineering agency of the federal government. Federal R&D spending by the NSF is slowly increasing. Its budget was \$2.1 billion in 1990 and \$2.3 billion in 1991.⁷²

In short, the United States currently lacks the necessary governmental organization to effectively create and implement strategic technology policy on a national scale. Poor coordination, lack of

62. *Id.*

63. *Id.*

64. *Id.*

65. COUNCIL ON COMPETITIVENESS, *supra* note 17, at 27.

66. *Id.*

67. *Id.*

68. Elizabeth Corcoran, *Talking Policy: The Administration Devises An Industrial Policy-Sort Of*, SCI. AM., June 1990, at 82, 82.

69. *See id.*

70. *Id.*

71. *See id.* at 82, 84.

72. Davey, *supra* note 59, at 9-10.

power, and inadequate funding are among the major problems that prevent the federal agencies from effectively promoting the commercialization of technology.

C. *Recent Federal Initiatives*

In the 1980s the federal government recognized the impact of technology development on the competitiveness of the American economy. The federal government began to promote policies and programs designed to address the issue. During the 1980s, the U.S. government launched several significant technology initiatives including: (1) support for technological innovation; (2) tax credit for R&D expenditures; (3) revisions of U.S. antitrust laws; (4) enactment of and support for the Semiconductor Manufacturing Technology Proposal (SEMATECH); and (5) other miscellaneous technology policy initiatives.

First, the decade began with legislation to promote the transfer of technology from federal laboratories to the private sector. In 1980, Congress passed the Stevenson-Wydler Technology Innovation Act⁷³ (1980 Act) which emphasized broad support of technological innovation.⁷⁴ The 1980 Act mandates a government-wide program for the transfer of technology from the federal laboratories to the private sector and authorized a network of centers for industrial technology.⁷⁵ Unfortunately, the federal government never fully implemented the 1980 Act, largely due to lack of adequate funding.

In 1986, Congress passed the Federal Technology Transfer Act,⁷⁶ known as the Stevenson-Wydler Amendments. The 1986 Amendments essentially reaffirmed the 1980 Act and strengthened some of its provisions. The 1980 Act required each of the nation's more than seven hundred federal laboratories to establish an Office of Research and Technology Applications which would be responsible for technology transfers from the federal laboratories to the private sector.⁷⁷ The 1980 Act also required each laboratory to participate in the Federal Laboratory Consortium, which "operates

73. Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311 (1980) (codified as amended at 15 U.S.C. §§ 3701-15 (1988)).

74. *Id.*

75. *Id.* at § 6 (codified as amended at 15 U.S.C. § 3705 (1988)).

76. Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, 100 Stat. 1785 (1986).

77. Stevenson-Wydler Technology Innovation Act of 1980 § 11 (codified as amended at 15 U.S.C. § 3710 (1988)); see also John H. Moore, *Innovation, Technology and Knowledge Transfers, East and West*, 32 EUR. ECON. REV., 591, 594.

as an information clearinghouse for Federal laboratories and potential technology users.”⁷⁸ The 1986 Amendments expanded the Federal Laboratory Consortium to include all federally owned and financed laboratories.⁷⁹

Second, Congress used the Internal Revenue Code to promote technological innovation. In 1981, the Economic Recovery Tax Act⁸⁰ was enacted in which Congress created a temporary 25% tax credit for R&D expenditures in excess of the firm’s expenditures in the base period, which generally encompassed the firm’s previous three years.⁸¹ The Act also contained a sunset provision under which the credit would expire at the end of 1985,⁸² the credit however has been extended.

Congress intended the tax credit to encourage the private sector to increase its R&D spending. However, evidence tends to indicate that the tax credit did little to increase private sector R&D expenditure.⁸³ R&D tax credits may have raised R&D expenditures as little as 1%.⁸⁴ The reason for the small impact of the tax credit on R&D expenditures may be due to the restrictive nature of the “base amount” used in calculating the tax credit.⁸⁵

Congress further diminished the effectiveness of the R&D tax credit by cutting the amount of the credit from 25% to 20% in the Tax Reform Act of 1986.⁸⁶ Furthermore, by reducing the R&D tax credit, Congress demonstrated to the private sector that the tax incentive could not be relied upon and could be reduced or discarded by Congress on short notice. However, R&D is inherently a long term investment, and firms must engage in advance R&D planning in order to use it successfully.

Changes in the method by which the credit is calculated occurred in the Omnibus Budget Reconciliation Act of 1989.⁸⁷ The

78. Moore, *supra* note 77, at 594; see also Stevenson-Wydler Technology Innovation Act of 1980 § 11 (codified as amended at 15 U.S.C. § 3710 (1988)).

79. Moore, *supra* note 77, at 594.

80. Economic Recovery Tax Act of 1981, Pub. L. No. 97-34, 95 Stat. 172 (1981).

81. *Id.* § 221, 95 Stat. at 241. See also Edwin Mansfield, *The R&D Tax Credit and Other Technology Policy Issues*, (Papers and Proceedings of the 98th Annual Meeting of the American Economic Association) 76 THE AM. ECON. REV., No. 2, at 190, 190 (1986).

82. Economic Recovery Tax Act of 1981 § 221, 95 Stat. at 247.

83. See Mansfield, *supra* note 81, at 190.

84. *Id.*

85. *Id.* at 191.

86. Tax Reform Act of 1986, Pub. L. No. 99-514, § 231(c), 100 Stat. 2085, 2175 (1986) (codified as amended at IRC § 41 (1988)).

87. Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 7110, 103 Stat. 2106, 2322-26 (1989); see also David L. Brumbaugh, *The Research and Experimentation Tax Credit*, CONG. RES. SERVICE ISSUE BRIEF, May 9, 1991, at 4.

changes focused on the base amount which was designed to improve the incentive effect of the credit.⁸⁸ An additional change extended "credit eligibility to R&D related to a firm's prospective line of business."⁸⁹ The fiscal year 1992 budget includes a proposal to make the R&D tax credit permanent at its current 20% rate,⁹⁰ although at the present time, the uncertainty of the tax credit's future inhibits its use by the private sector.

Third, antitrust laws have traditionally served to encourage innovative behavior, but they have also engendered hesitancy on the part of business to engage in joint research and development ventures that would permit the most efficient use of human and capital resources. In the past, even the threat of antitrust action would likely have ended any joint R&D project. Congress enacted the National Cooperative Research Act⁹¹ in 1984 to remedy this situation. The law takes the approach that joint research ventures are not to be judged illegal "per se."⁹² Rather, each venture is judged on a reasonableness basis, taking into account all relevant factors affecting competition.⁹³ The 1984 Act also eliminates treble damages awards for joint research ventures found in violation of the antitrust laws⁹⁴ if prior disclosure has been made to the Department of Justice and the Federal Trade Commission.⁹⁵ The law explicitly excludes production activities in order to maintain compliance with the Sherman and Clayton Antitrust Acts.⁹⁶

Despite these changes, firms are still wary of being involved in joint activities for fear of unknown consequences which may arise if the government decides that the joint ventures engage in production, as opposed to research activities. The U.S. Office of Technology Assessment has stated:

Whether modifying the antitrust laws or their enforcement would unleash a great deal of cooperative work, and whether such changes would substantially improve manufacturing competitiveness, is unknown Changes in antitrust law and en-

88. Brumbaugh, *supra* note 87, at 4.

89. *Id.*

90. *Id.*

91. National Cooperative Research Act of 1984, Pub. L. No. 98-462, 98 Stat. 1815 (1984) (codified as amended at 15 U.S.C. §§ 4301-05 (1988)).

92. Schacht, *supra* note 23, at 9; see also National Cooperative Research Act of 1984 § 4302.

93. National Cooperative Research Act of 1984 § 4302.

94. *Id.* at § 4303.

95. *Id.* at § 4305.

96. S. REP. NO. 427, 98th Cong., 2nd Sess. 12-13 (1984), reprinted in 1984 U.S.C.A.N. 3105, 3109.

forcement should be made cautiously, but they deserve serious consideration.⁹⁷

The semiconductor companies that need collective action in order to compete with the Japanese are particularly concerned with the antitrust aspects of joint ventures. These cutting edge companies wish to band together to manufacture memory chips, but this would still violate the antitrust laws.

The newest answer is the proposed National Cooperative Production Act which goes farther than the National Cooperative Research Act of 1984 since it allows for joint production of innovations among companies.⁹⁸ This bill has two key provisions: (1) "[i]t would relieve government sanctioned joint ventures from treble-damage phobia;" and (2) it would incorporate into law court decisions that "cast a warmer eye on joint-production accords."⁹⁹ However, a dispute over the exclusion of co-production ventures with more than 30% foreign ownership has delayed passage of the bill.¹⁰⁰ The problem with this restriction is that often it is the foreign firms that not only have the technology, but also the capital needed to ensure the success of a venture.¹⁰¹ The main beneficiaries of this bill would be the high technology industries that spawn the critical innovations.¹⁰²

Fourth, in 1987, Congress enacted the Semiconductor Manufacturing Technology, or SEMATECH, initiative "to assist its U.S. member companies to develop new processes for semiconductor manufacturing."¹⁰³ The initial impetus for the SEMATECH proposal was provided by a DoD Defense Science Board study, *Report of Defense Science Board Task Force on Defense Semiconductor Dependency*.¹⁰⁴ The report highlighted the increasing foreign control of the semiconductor market and ramifications for the U.S. military if the primary source of this technology was foreign.¹⁰⁵ The study provided two justifications for a federal government role in the

97. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. Congress, *Making Things Better: Competing in Manufacturing* 30 (1990).

98. Paul Magnusson, *The Antitrust Ball and Chain Hobbling High Tech*, BUS. WK., July 29, 1991, at 34, 34.

99. *Id.*

100. *Id.*

101. *Id.*

102. *See id.*

103. Glenn J. McLoughlin, *SEMATECH: The Semiconductor Manufacturing Technology Initiative*, CONG. RES. SERVICE REP., Feb. 7, 1991 at 1.

104. *Id.*

105. *Id.*

manufacturing of commercial semiconductor chips.¹⁰⁶

First, the pressure of rapid technological innovation and short product life cycles had worked "against longer-term R&D for next generation manufacturing equipment."¹⁰⁷ The government, through DARPA, would be able to provide the industry with the funding stability necessary for long term growth.¹⁰⁸ Second, the study recognized that semiconductor technologies are a vital element of the U.S. electronics industry, and the demise of these technologies could undermine a significant part of the entire U.S. electronics industry.¹⁰⁹

Legislation to fund SEMATECH was included in the Defense Appropriations Bill for Fiscal Year 1988¹¹⁰ which calls for joint federal-industry funding of \$100 million each year through 1992.¹¹¹ Fourteen U.S. companies became charter members of SEMATECH while federal management responsibilities fell to DARPA which acts as the "silent" fifteenth partner.¹¹²

Most assessments of SEMATECH have been positive, but the idea of consortia has not been without critics. Consortia have often failed due to seven generic problems: recruiting personnel, obtaining resources, obtaining new partners, confused decision making, complex legal issues, membership turnover, and evaluating and producing outputs.¹¹³ SEMATECH has managed to avoid these problems and build a clean room and chip fabrication line in only thirty-two weeks, an impressive accomplishment.¹¹⁴

Federal funding for SEMATECH is about to run dry. SEMATECH II has been proposed as a "second five-year plan that will broaden SEMATECH's mission and its role within the U.S. semiconductor industry."¹¹⁵ The federal role in this second project is still unclear, although it is certain some federal support will be requested by the consortium.¹¹⁶

106. *Id.*

107. *Id.*

108. McLoughlin, *supra* note 103, at 1.

109. *Id.* at 1-2.

110. National Defense Authorization Act for Fiscal Years 1988 and 1989, Pub. L. No. 100-180, 101 Stat. 1019 (1987).

111. Glenn J. McLoughlin, *Semiconductor Manufacturing Technology Proposal: SEMATECH*, CONG. RES. SERVICE ISSUE BRIEF, Dec. 19, 1991, at 4; *see also* 15 U.S.C. § 4602 (1988).

112. McLoughlin, *supra* note 111, at 4.

113. William M. Evan & Paul Olk, *R&D Consortia: A New U.S. Organizational Form*, SLOAN MGMT. REV., Spring 1990, at 37, 41.

114. Lee Smith, *Can Consortiums Defeat Japan?*, FORTUNE, June 5, 1989, at 245, 254.

115. McLoughlin, *supra* note 111, at 7.

116. *Id.*

Fifth, the United States has undertaken a variety of technology policy initiatives. Other noteworthy federal initiatives include the creation of the annual Malcom Baldrige Quality Award,¹¹⁷ the elevation of the National Science Advisor to the Assistant to the President for Science and Technology Policy,¹¹⁸ and the establishment of the Advanced Technology Program (ATP) within the DoC.¹¹⁹

III. LOOKING TO THE FUTURE

In 1992, the United States is at a technology policy crossroads. Free market advocates argue that government has no role in technology and industry as a venture capitalist, believing that such a role will only result in supporting dying industries. Private sector plans envision a partnership between government and business with government taking the lead in the early stages where business is unable to maintain long term funding. The U.S. government has taken tentative steps toward adopting an industrial and technology policy by formulating lists of critical technologies. Nevertheless, in the face of a lagging economy, it is evident that some action beyond list-making is necessary. This section explains the alternative viewpoints of free market advocates, and private sector planners.

A. *Free Market Position*

Since the birth of this country, an ongoing debate has existed over whether the federal government should formulate an industrial policy and play an active role in it.¹²⁰ Indeed, the debate can be dated to the disagreements between Alexander Hamilton and Thomas Jefferson.¹²¹ The mercantilism of Hamilton, denounced by Jefferson, advocated "protectionist tariffs, bounties, and premiums to nurture its infant industries."¹²² Since that time, the free market position has been the federal government's stated policy, but as the industrial and technological sector weakens, these free marketers are finding it necessary to defend their position and decry the perils of a national industrial policy.¹²³

Free market advocates take the view that the federal government should not get involved in promoting the commercialization

117. COUNCIL ON COMPETITIVENESS, *supra* note 14, at 17.

118. *Id.*

119. Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, § 5131, 102 Stat. 1107, 1439-41 (1988); *see also* 15 U.S.C. § 278n (1988).

120. *Industrial Policy: Is it the answer?*, BUS. WK., July 4, 1983, at 54, 54.

121. *Id.*

122. *Id.*

123. *See id.*

of technology.¹²⁴ Specifically, they assert that any type of industrial policy will stifle economic growth, slow down the shift of resources to productive industries by trying to shore up declining industries, and waste money on "targeted growth" industries that may have no commercial future.¹²⁵ An industrial policy would also create many layers of bureaucrats who will tinker with planning, bailouts, and loan guarantees.¹²⁶

One of the main objectives of the free market advocates to an industrial policy focuses on politicization. Free marketers assert that Congress will not invest any group with authority to make policy because the new administrative body would cut into the prerogatives of the professional politicians. Politicians are greatly influenced by the entrenched management of big industries and interest groups who "will manipulate any industrial policy to promote their own interests rather than those of the whole country."¹²⁷ Many free market advocates vow that the government as entrepreneur is destined for failure.¹²⁸ They point to the government's supervision of the railroads into bankruptcy, regulatory destruction of interurban transportation, and regulation of thousands of banks out of existence in the 1930s.¹²⁹

One of the key advocates of the free market position is Charles L. Schultze, former chairman of the Council of Economic Advisors under President Jimmy Carter.¹³⁰ Schultze claims that the phrase "industrial policy" refers to "a loose collection of similar diagnoses and proposals" that rely on two explicit propositions: (1) "the U.S. has been de-industrializing;" and (2) "some other countries - Japan being the preeminent example - have developed governmental policies that successfully promote vigorous industrial growth."¹³¹ According to Schultze, the need for industrial policy rests upon two implicit propositions: (1) "the government [possesses] the analytical capability to determine with greater success than market forces what industrial structure is appropriate, who the potential winners are, which of the losers should be saved, and how they should be restructured;" and (2) "the American political system [can] make

124. *See id.* at 57.

125. *Industrial Policy*, *supra* note 120, at 57.

126. *Id.*

127. Gary S. Becker, *The Best Industrial Policy is None at All*, BUS. WK., August 5, 1985, at 14, 14.

128. *See Industrial Policy*, *supra* note 120, at 57.

129. *Id.*

130. Charles L. Schultze, *Industrial Policy: A Dissent*, THE BROOKINGS REV., Fall 1983, at 3, 3.

131. *Id.* at 3-4.

such critical choices among firms, individuals, and regions on the basis of economic criteria rather than political pressures.”¹³²

Schultze concludes that none of these propositions reflect reality.¹³³ “America has not been de-industrializing.”¹³⁴ Although economic performance has faltered at times, relative to the industries of other countries, U.S. industry has performed well by most standards.¹³⁵ Schultze maintains that there is no evidence that the sharp decline in productivity growth “stems from a tendency for the private market system to allocate investment to the ‘wrong’ places[,] away from the manufacturing sector or, within manufacturing, to the wrong firms or industries.”¹³⁶

Examining the flourishing of the post-war Japanese economy, Schultze downplays the role of industrial policy under the leadership of the Ministry of International Trade and Industry (MITI).¹³⁷ He asserts that the “huge savings rate, aggressive business leaders, and . . . backlog of modern technology waiting to be exploited” are the main reasons that Japan has prospered.¹³⁸ Outside of Japan, the failures of industrial policy are more evident; the Concorde in France and Britain,¹³⁹ and the French state-sponsored computer grant to the French company Groupe Bull SA¹⁴⁰ “are examples of costly, futile government investments in [R&D].”¹⁴¹

Schultze flatly concludes that it is impossible to plan a successful industrial structure¹⁴² because “a set of economic criteria that determine what gives different countries preeminence in particular lines of business” simply does not exist.¹⁴³ Also, the American political system was not designed to bring order and authority needed by an industrial policy, but to “constrain legislative and executive authorities so that they could not make arbitrary and invidious choices among individuals” and groups.¹⁴⁴ If attempted, the end result would be misallocated resources, reduced industrial effi-

132. *Id.* at 4.

133. *Id.*

134. *Id.*

135. Schultze, *supra* note 130, at 4.

136. *Id.* at 6.

137. *Id.*

138. *Id.* at 7.

139. *Industrial Policy*, *supra* note 120, at 61.

140. Michael Schrage, *Lessons in How Not To Develop an Industrial Policy*, WASH. POST, April 5, 1991, at F3.

141. *Industrial Policy*, *supra* note 120, at 61.

142. Schultze, *supra* note 130, at 9.

143. *Id.* at 7.

144. *Id.* at 10.

ciency incentives, and blunted competitive forces.¹⁴⁵

For the free market believers, any industrial policy will be reduced to the government picking winners and losers.¹⁴⁶ They emphasize government's present inability to be effective through its "patchwork mess" of "existing tax policy, antitrust regulation, and all the other elements which have become a kind of de facto industrial policy."¹⁴⁷ For them, "American grit and determination" will be the force that drives U.S. industry, not government policy.¹⁴⁸

Despite the naysayers, the beginnings of a national industrial policy for the 1990s are becoming visible. This section next analyzes (1) private sector plans offered by the Council on Competitiveness and the Carnegie Commission, (2) governmental efforts focusing on efforts by the DoD, DoC, and the National Critical Technologies Panel to identify critical technologies and (3) more far reaching Congressional proposals for governmental involvement.

B. *Private Sector Plans*

Two private organizations that have greatly influenced governmental policymakers to reevaluate the role of the public sector in helping U.S. industry are the Council on Competitiveness and the Carnegie Commission. These two diverse and well-respected groups have focused attention on critical problems that face this nation's industries.

1. Council on Competitiveness

In 1986, John Young, CEO of Hewlett-Packard, founded the Council on Competitiveness as a non-profit, nonpartisan organization of chief executives from business, higher education and organized labor. The Council's goal focuses on improving the ability of American companies to compete effectively in world markets. The Council has a three part agenda: to increase public awareness of the breadth and severity of America's economic problems; to mobilize the political will required to set the United States on a new and positive economic course; and to assist in the development of specific public policies and private initiatives.¹⁴⁹ The Council's policy positions are based on the assumption that improving competitive-

145. *Id.*

146. John S. McClenahan, *Now Do We Need a National Industrial Policy?*, *INDUSTRY WK.*, March 18, 1991, at 56, 57.

147. *Id.*

148. *Id.* at 58.

149. COUNCIL ON COMPETITIVENESS, *supra* note 14.

ness will only occur through a series of incremental steps that involve all sectors, including business, labor, academia, and government. The Council has issued a series of pragmatic, action-oriented recommendations upon which practical policies can be built.

One of the Council's first reports, *America's Competitive Crisis: Confronting the New Reality*,¹⁵⁰ played an important role in structuring the initial competitiveness debate. The Council continued its study of the competitiveness crisis with *Picking Up the Pace: The Commercial Challenge to American Innovation*.¹⁵¹ This report discussed how and to what extent America's once commanding technological lead has disappeared. Its policy recommendations address ways the federal government can facilitate the commercialization of technology.

The Council made four broad recommendations in *Picking Up the Pace*, each addressing a key policy issue.¹⁵² First, "the federal government should improve the macroeconomic environment that affects the private sector's ability to develop and apply technology."¹⁵³ Such an improvement could be made by making "fiscal policy more supportive of private sector efforts to commercialize technology" and by strengthening U.S. trade policy for technology.¹⁵⁴ Fiscal policy should be directed at credible multi-year deficit reduction and the promotion of savings and long term investment.¹⁵⁵ Trade policy should focus on opening foreign high-technology markets and improving protection of intellectual property abroad.¹⁵⁶

Second, the Council recommended that "the federal government should improve the machinery for making technology policy."¹⁵⁷ Specifically, an Assistant to the President for Science and Technology should be appointed as a cabinet level position.¹⁵⁸ Technology policy should also "rationalize the involvement of Congress in technology-related issues" by making R&D tax provisions consistent, increasing "funding for government agencies that contribute to the commercial application of technology," and creating

150. COUNCIL ON COMPETITIVENESS, *AMERICA'S COMPETITIVENESS CRISIS: CONFRONTING THE NEW REALITY* (1987).

151. COUNCIL ON COMPETITIVENESS, *supra* note 17.

152. *Id.* at 4-7.

153. *Id.* at 4.

154. COUNCIL ON COMPETITIVENESS, *supra* note 17.

155. *Id.*

156. *Id.*

157. *Id.*

158. *Id.*

"a legal and regulatory environment more conducive to the commercial application of technology."¹⁵⁹

Third, the Council recommended that "the federal government should increase its investment in the education, facilities and equipment that constitute the nation's technological infrastructure" by initiating a faculty-development program for science and engineering and modernizing university research facilities with a \$10 billion dollar program.¹⁶⁰

Fourth, the Council concluded by recommending that "the federal government . . . widen the focus of national research and development efforts."¹⁶¹ Specifically, the Council indicated that the federal government should re-evaluate "the agenda and purpose of the federal laboratories and their relationship with industry," facilitate "cooperative generic manufacturing technology," improve "federal coordination with state technology programs," and encourage Defense Department efforts to strengthen the U.S. industrial base.¹⁶²

In March, 1991, the Council published *Gaining New Ground: Technology Priorities for America's Future*.¹⁶³ This report represents a pioneering effort to examine the U.S. strategic technology needs for the 1990s. The report identifies, on a sector by sector basis, strategic industrial priorities in science and technology. The Council worked closely with senior technology experts from nine sectors of U.S. industry to identify the technologies deemed critical to each industry.¹⁶⁴ The Council verified the list of critical technologies with leading executives from universities, labor unions, and other specialists.¹⁶⁵ The analysis of each sector focused on the sector's competitive position, the technologies that are important to it, how it develops and uses technology, its performance in developing technology, and the factors supporting and inhibiting its technology development.¹⁶⁶ As a result of this exhaustive analysis, the Council determined the critical technologies that need to be developed and assessed the impact of government policies on the various sectors' competitiveness. The Council compiled the findings and made pol-

159. COUNCIL ON COMPETITIVENESS, *supra* note 17, at 5-6.

160. *Id.* at 6-7.

161. *Id.* at 7.

162. *Id.*

163. COUNCIL ON COMPETITIVENESS, *supra* note 14.

164. *Id.* at i.

165. *Id.*

166. *Id.* at 55.

icy recommendations to the government on how to better facilitate technology development in the nation.

In its March 1991 report, the Council listed six key findings:

- 1) "there [exists] a broad domestic and international consensus about the critical generic technologies driving economic growth and competitiveness,"¹⁶⁷
- 2) "the U.S. position in many critical technologies is slipping and, in some cases, has been lost altogether[.]" with future trends not looking encouraging,¹⁶⁸
- 3) "foreign governments are systematically pursuing leadership in critical technologies,"¹⁶⁹
- 4) "U.S. public policy does not adequately support American leadership in [these] technologies, and U.S. national priorities do not sufficiently address issues related to the role of technology in U.S. competitiveness,"¹⁷⁰
- 5) "most of the technologies that will drive economic growth over the next decade already exist, and industry needs to improve its ability to convert them into marketable products and services,"¹⁷¹
- 6) "America's research universities constitute a great national asset, but their focus on technology and competitiveness is limited,"¹⁷²

Based upon these findings, the 1991 report concluded that "in order to create quality jobs, generate strong economic growth and safeguard national security, the U.S. government and private sector should work together to develop coherent policies to ensure U.S. leadership in the development, use and commercialization of technology."¹⁷³

The Council recommended that the President make technology leadership a national priority in order to enhance U.S. economic competitiveness.¹⁷⁴ The Council asserted that the federal and state governments should "develop policies and implement programs to ensure that America has a world-class technology infrastructure."¹⁷⁵ In addition, because technological advancements require vigorous private sector efforts, the Council argued that "U.S. indus-

167. *Id.* at 1.

168. COUNCIL ON COMPETITIVENESS, *supra* note 14, at 2.

169. *Id.*

170. *Id.*

171. *Id.* at 3.

172. *Id.*

173. COUNCIL ON COMPETITIVENESS, *supra* note 14, at 3.

174. *Id.*

175. *Id.* at 4.

try should establish more effective technology networks to help it compete in the international marketplace."¹⁷⁶ The Council further argued that "U.S. firms should set a goal to meet and surpass the best commercialization practices of their competitors."¹⁷⁷ Finally, the Council recommended that, "while keeping their basic research programs strong, universities should develop closer ties to industry so that education and research programs contribute more effectively to the real . . . needs of the manufacturing and service sectors."¹⁷⁸

2. The Carnegie Commission

In 1988, the Carnegie Corporation of New York created the Carnegie Commission on Science, Technology, and Government.¹⁷⁹ The Commission's purpose focuses on helping government institutions respond to advances in science and technology and seek out ways to make this relationship more effective.¹⁸⁰

In September, 1991, the Commission published *Technology and Economic Performance: Organizing the Executive Branch for a Stronger National Technology Base*,¹⁸¹ a "how-to" manual for the government to provide better support for technology development.¹⁸² While emphasizing that the primary responsibility for the advancement of commercial technology rests with private industry, the Commission called for a greater federal role in supporting "generic" technologies that contribute to both commercial and military uses.¹⁸³ Through this report, the Commission attempts to provide the executive branch with some "first steps" toward implementing a technology policy.¹⁸⁴

The Commission offered four specific proposals. First, the Commission recommended the transformation of DARPA into NARPA, the National Advanced Research Projects Agency.¹⁸⁵ The "renamed agency would focus more on dual-use technolog[ies], those technologies that are useful both in defense and commercial

176. *Id.* at 5.

177. *Id.*

178. COUNCIL ON COMPETITIVENESS, *supra* note 14, at 6.

179. Council on Competitiveness, *Technology Policy: Blueprint Provided for Government, CHALLENGES*, October 1991, at 1, 4 [hereinafter *Technology Policy*].

180. *Id.*

181. CARNEGIE COMMISSION ON SCIENCE, TECHNOLOGY, AND GOVERNMENT, *TECHNOLOGY AND ECONOMIC PERFORMANCE: ORGANIZING THE EXECUTIVE BRANCH FOR A STRONGER NATIONAL TECHNOLOGY BASE* (1991) [hereinafter *CARNEGIE COMMISSION*].

182. *Technology Policy*, *supra* note 179, at 1.

183. *Id.* at 1, 4; *see also* CARNEGIE COMMISSION, *supra* note 181, at 6.

184. *Technology Policy*, *supra* note 179, at 4.

185. *Id.*; *see also* CARNEGIE COMMISSION, *supra* note 181, at 7.

markets.”¹⁸⁶ Because defense budgets are likely to decrease during the 1990s, NARPA would have to collaborate extensively with commercial industry.¹⁸⁷ The agency would still support purely military technologies, but it would also enter into cooperative ventures and develop techniques for commercial diffusion of technology.¹⁸⁸

Second, the Commission suggested designating the President’s Office of Science and Technology Policy “as the focal point for identifying and formulating technology policy issues.”¹⁸⁹ The Office of Science and Technology Policy, the Commission concluded, should also provide support for technology program development and evaluation.¹⁹⁰

Third, the Commission concluded that the National Security Council should take the lead within the executive branch “in coordinating and integrating the various policy perspectives on matters that link national security, economic performance and technology strength.”¹⁹¹

Fourth, within the Commerce Department, NIST “would have the central responsibility for supporting pre-competitive, generic research and development not within the purview of other government agencies or departments.”¹⁹²

These two private groups, the Council on Competitiveness and the Carnegie Commission, have taken the lead in propelling the federal government into action. In their reports, they focused on the deteriorating areas of U.S. competitiveness and suggested ways to change the current course. The alarm that these groups sounded led the government to begin to study the problems. This eventually resulted in reports by the Department of Defense, the Department of Commerce and the National Critical Technologies Panel.

C. Government Plans

Efforts in the early 1980s to cut back the role of government resulted from the widespread view that strong government and effi-

186. *Technology Policy*, *supra* note 179, at 4; *see also* CARNEGIE COMMISSION, *supra* note 181, at 40.

187. *Technology Policy*, *supra* note 179, at 4; *see also* CARNEGIE COMMISSION, *supra* note 181, at 40.

188. *Technology Policy*, *supra* note 179, at 4; *see also* CARNEGIE COMMISSION, *supra* note 181 at 40.

189. *Technology Policy*, *supra* note 179, at 4; *see also* CARNEGIE COMMISSION, *supra* note 181, at 25.

190. *Technology Policy*, *supra* note 179, at 4; *see also* CARNEGIE COMMISSION, *supra* note 181, at 25.

191. *Technology Policy*, *supra* note 179, at 4.

192. *Id.*; *see also* CARNEGIE COMMISSION, *supra* note 181, at 7.

cient private business are adversaries.¹⁹³ After ten years of decreased market share, lower educational performance, and declining productivity, many have realized that cutting back on government intervention may have not helped U.S. industry. In short, a need exists to reinvest and refocus government's involvement in business and technology.

Beginning in the late 1980s, this view of a new role for government found fruition in the concept of critical technologies. The advocates of massive federal funding for commercial R&D put pressure on the government to help U.S. firms improve their ability to reach out and bring technology to the market rapidly. Government already spends \$70 billion a year on science and technology, but as noted, the focus has been mostly military. In the past, commercial industries were able to rely on defense spinoffs, but that is no longer feasible. The supporters of a technology policy want to shift federal spending from defense to commercial applications, change the mission of national laboratories from defense to industrial technology, have the President make competitiveness a top priority, and increase efforts to spread advanced manufacturing methods to all U.S. firms.¹⁹⁴

In 1988, the government, through the Defense Department, took its first step in becoming involved in facilitating the development of critical technology. Since that year, the Department of Commerce and the National Critical Technologies Panel, along with the President's Office of Science and Technology Policy, have also developed critical technologies reports. Each report reviews the current situation, future trends, and makes suggestions on the direction both government and industry should take.

The aim of governmental intervention in critical technologies is to increase U.S. competitiveness. The Bush administration is not advocating an industrial policy, but is supporting pre-competitive, generic technology.¹⁹⁵

1. Department of Defense

Since 1989, the Department of Defense has released annual critical technologies plans.¹⁹⁶ The purpose of these reports is to

193. See Robert Kuttner, *Why Business Needs a Stronger - and Wiser - Uncle Sam*, BUS. WK., June 3, 1991, at 16, 16.

194. *Id.*

195. *Bush Science Aide Issues a Statement to Quell Criticism*, WALL ST. J., May 17, 1991, at A11.

196. U.S. DEPARTMENT OF DEFENSE, CRITICAL TECHNOLOGIES PLAN ES-1 (1989).

identify the technologies that will maintain U.S. military superiority.¹⁹⁷ These reports also attempt to provide guidelines for long term investment planning.¹⁹⁸ Examining the progression of the plans, it is evident that the amount of information and participation has drastically increased. These plans were the first plans mandated by Congress that focus primarily on critical technologies.

In response to the requirements contained in the National Defense Authorization Act, Fiscal Year 1989,¹⁹⁹ the DoD released its first Critical Technologies Plan in March, 1989.²⁰⁰ The Act required the Defense Department, with the assistance of the Department of Energy, to annually provide Congress with a critical technology plan.²⁰¹ According to Congress, critical technologies are “the technologies most essential to develop in order to ensure the long term qualitative superiority of the United States weapon system.”²⁰²

The Department of Defense’s 1989 report contained considerable information about the procedural aspects of formulating the plan.²⁰³ The plan resulted from a series of meetings involving representatives of the Department of Defense, the Department of Energy, and the agencies within these departments responsible for science and technology programs.²⁰⁴

In the 1989 report, the DoD defined critical technologies as “technologies with great promise of ensuring the long-term superiority of the United States weapon systems.”²⁰⁵ Nuclear weapons were purposely excluded.²⁰⁶ The report emphasized that the mere promotion of critical technologies will not suffice; critical technologies must be “integrated into a balanced science and technology program.”²⁰⁷

The Department of Defense already had a science and technology (S&T) investment strategy which shared and continues to share the same objectives as the Critical Technologies Plan, namely, plan-

197. *See id.*

198. *See id.* at ES-2.

199. National Defense Authorization Act, Fiscal Year 1989, Pub. L. No. 100-456, 102 Stat. 1918 (1988).

200. U.S. DEPARTMENT OF DEFENSE, *supra* note 196, at 1.

201. *Id.*

202. *Id.* at 1.

203. *Id.* at 2-3.

204. *Id.* at 1.

205. U.S. DEPARTMENT OF DEFENSE, *supra* note 196, at ES-1.

206. *Id.*

207. *Id.*

ning technology to meet defense needs.²⁰⁸ The difference is that the Critical Technologies Plan focuses on the "star performers" while the S&T investment strategy takes into account the "whole team."²⁰⁹ The Critical Technologies Plan, however, emphasized that stability and perseverance in the overall program are vital to ensure yearly improvements.²¹⁰

The 1989 Plan selected twenty-two critical technologies²¹¹ based upon their potential in the performance and quality design criteria.²¹² Under the performance criteria, critical technologies must either "enhance performance of conventional weapons systems" or "provide new military capabilities."²¹³ Under the quality design criteria, critical technologies must either "improve weapon systems availability and dependability" or "improve weapon systems affordability."²¹⁴

Some of the critical technologies chosen have high potential for rewards, but are also high risk.²¹⁵ To reduce this risk, the 1989 report recommended that a technology in its conceptual stage follow several alternative approaches.²¹⁶ At the "proof-of-feasibility" stage, the most promising approaches can be identified and future development options can be narrowed.²¹⁷ While at the "demonstration" stage of development, a particular approach can be brought to the point of transitioning into a system.²¹⁸

In the Department's overall assessment, the 1989 report concluded that the then present defense programs emphasized direct support of research and development in universities and industries.²¹⁹ The 1989 report optimistically maintained that, as of 1989, the United States continued to be the world leader in technological

208. *Id.* at ES-2.

209. *Id.*

210. U.S. DEPARTMENT OF DEFENSE, *supra* note 196, at ES-2.

211. *Id.* at ES-1, ES-2. The technologies were: Microelectronic Circuits and Their Fabrication, Preparation of GaAs and Other Compound Semi-Conductors, Software Producibility, Parallel Computer Architectures, Machine Intelligence/Robotics, Simulation and Modeling, Integrated Optics, Fiber Optics, Sensitive Radars, Passive Sensors, Automatic Target Recognition, Phased Arrays, Data Fusion, Signature Control, Computational Fluid Dynamics, Air Breathing Propulsion, High Power Microwaves, Pulsed Power, Hypervelocity Projectiles, High-Temperature/High-Strength/Light-Weight Composite Materials, Superconductivity, and Biotechnology Materials and Processing. *Id.*

212. *Id.* at 5.

213. *Id.*

214. *Id.*

215. U.S. DEPARTMENT OF DEFENSE, *supra* note 196, at 2.

216. *Id.*

217. *Id.*

218. *Id.*

219. *Id.* at 9.

development, but conceded that in key niches of technology, other countries were aggressively moving ahead.²²⁰

The 1990 Defense Department Critical Technologies Plan,²²¹ required by the National Defense Authorization Act for Fiscal Years 1990 and 1991²²² expanded upon the 1989 plan. The 1990 plan was prepared by a group chaired by the Secretary of Defense with representatives from, among others, the Army, Navy, Air Force, DARPA, Defense Intelligence Agency (DIA), Department of Energy (DoE), and the National Laboratories in Los Alamo, Livermore, and Sandia.²²³

The 1990 Plan reduced the number of critical technologies from twenty-two to twenty.²²⁴ From the 1989 Plan's list, fifteen titles remained the same, two technologies (integrated optics and fiber optics) were combined under one title, two titles (high power microwaves and phased arrays) were removed, although aspects of these were included under pulsed power, signal processing, and sensitive radars, and two new technologies (high energy density materials and weapon system environment) were introduced.²²⁵

In choosing critical technologies, the 1990 report enlarged the selection criteria, adding "multiple use."²²⁶ Under multiple use criteria, the technologies were judged on their "pervasiveness in major weapon systems" and their "strengthening [of] the industrial base."²²⁷

The 1990 Plan prioritized the twenty critical technologies into three categories.²²⁸ Group A consisted of technologies that were the most pervasive and judged to be of top priority.²²⁹ Included in group A were composite materials, computational fluid dynamics,

220. U.S. DEPARTMENT OF DEFENSE, *supra* note 196, at 10.

221. UNITED STATES DEPARTMENT OF DEFENSE, CRITICAL TECHNOLOGIES PLAN (1990).

222. National Defense Authorization Act for Fiscal Years 1990 and 1991, Pub. L. No. 101-189, sec 842, § 2508, 103 Stat. 1352, 1512-14 (1989).

223. UNITED STATES DEPARTMENT OF DEFENSE, *supra* note 196, at 1.

224. *Id.* at ES-1. The technologies were: Semiconductor Materials and Microelectronic Circuits, Software Producibility, Parallel Computer Architectures, Machine Intelligence and Robotics, Simulation and Modeling, Photonics, Sensitive Radars, Passive Sensors, Signal Processing, Signature Control, Weapon System Environment, Data Fusion, Computational Fluid Dynamics, Air-Breathing Propulsion, Pulsed Power, Hypervelocity Projectiles, High Energy Density Materials, Composite Materials, Superconductivity, and Biotechnology Materials and Processes. *Id.*

225. *Id.* at 6.

226. *Id.* at 5. The 1989 selection criteria were performance and quality design. See *supra* note 137 and accompanying text.

227. *Id.*

228. U.S. DEPARTMENT OF DEFENSE, *supra* note 196, at 6.

229. *Id.* at 6-7.

data fusion, passive sensors, photonics, semiconductor materials and microelectronic circuits, signal processing and software producibility.²³⁰

Group B included "enabling technologies [that] offer[ed] the most immediate advances in weapon systems capabilities."²³¹ Included in group B were air-breathing propulsion, machine intelligence and robotics, parallel computer architectures, sensitive radars, signature control, simulation and modeling and weapon system environment.²³²

Selected for Group C were "principally emerging technologies whose applications [were] farthest in the future and most difficult to identify in detail."²³³ Included in group C were biotechnology materials and processes, high-energy density materials, hypervelocity projectiles, pulsed power and superconductivity.²³⁴

The 1991 Critical Technologies Plan²³⁵ was more comprehensive than earlier plans. Congressional mandate required the Plan to outline the twenty-one technologies²³⁶ and to document funding levels necessary for the advancement of each technology.²³⁷ The 1991 Plan represented an increased level of participation with input from DoE, DoC, National Science Foundation, and other interested private sector groups, including the Aerospace Industries Association, the Electronic Industries Association, and the National Security Industrial Association.²³⁸ The Plan also included a 1992 budget request and a proposed five year budget with \$232 million for DARPA to pursue technology objectives. The report formulated a "twenty-year view" for the DoD to provide for orderly, evolutionary improvements in weapon systems, generate innovative, highly leveraged breakthrough technologies and insert them into our mili-

230. *Id.* at 7.

231. *Id.*

232. *Id.*

233. U.S. DEPARTMENT OF DEFENSE, *supra* note 196, at 7.

234. *Id.*

235. UNITED STATES DEPARTMENT OF DEFENSE, CRITICAL TECHNOLOGIES PLAN (1991).

236. *Id.* at I-3. The technologies chosen were: Semiconductor Materials and Microelectronic Circuits, Software Engineering, High Performance Computing, Machine Intelligence and Robotics, Simulation and Modeling, Photonics, Sensitive Radar, Passive Sensors, Signal and Image Processing, Signature Control, Weapon System Environment, Data Fusion, Computational Fluid Dynamics, Air Breathing Propulsion, Pulsed Power, Hypervelocity Projectiles and Propulsion, High Energy Density Materials, Composite Materials, Superconductivity, Biotechnology, and Flexible Manufacturing. *Id.*

237. National Defense Authorization Act for Fiscal Year 1990 and 1991 sec 605, § 2508, 103 Stat. at 1512-13.

238. UNITED STATES DEPARTMENT OF DEFENSE, *supra* note 196, at I-1.

tary capability, and seek technological “trump cards” to sustain long-term dominance in the technological arms race.²³⁹ The 1991 report also contained what the Department called “themes” which were really broad goals such as producing quality products at an affordable cost, modernizing the Research, Development, Testing and Evaluation (RDT&E) establishment, and radically accelerating the development and use of flexible manufacturing and training technology.²⁴⁰

The 1991 report contained brief descriptions of each of the twenty-one critical technologies, its applications, and future potential.²⁴¹ The list of technologies changed little from the previous year. The 1991 Plan differs from the 1990 Plan in that it makes no effort to explicitly assign higher or lower priorities to any of the critical technologies.²⁴²

The 1991 report placed twenty-one critical technologies into five clusters:

- (1) computing/information,
- (2) sensing,
- (3) materials and manufacturing,
- (4) energy and material flow management, and
- (5) infrastructure.

The 1991 report used the cluster approach to demonstrate the high degree of technological interdependence.²⁴³

The 1991 report was the first defense report which emphasized dual-use technologies, noting that only six of the listed critical technologies were military-specific technologies.²⁴⁴ The remaining fifteen technologies have significant commercial application or potential in addition to their military significance.²⁴⁵

The 1989, 1990 and 1991 Critical Technologies Plans established a consistent need for development of certain technologies for military superiority. The progression of the plans demonstrate a widening focus, concentrating not only on military use, but also on commercial potential. These plans represent a pioneering Federal government effort toward identifying critical technologies.

239. *Id.* at II-1.

240. *Id.* at II-2.

241. *Id.* at III-1 - III-21.

242. *DoD Lists 21 Critical Technologies, includes Flexible Manufacturing*, Bureau of National Affairs, April 8, 1991, at A16.

243. *Id.*

244. *Id.*

245. *Id.*

2. Department of Commerce (DoC)

In the spring of 1990, the Technology Administration within the Department of Commerce published *Emerging Technologies, A Survey of Technological and Economic Opportunities*.²⁴⁶ The report sought to "provide a source of information to be used by industry, government and academia as programs and policies are developed to exploit new, emerging technologies."²⁴⁷

The DoC report defined an emerging technology as one having "a high probability of techn[ological] success for new products and applications that might have substantial markets within approximately ten years."²⁴⁸ An emerging technology might also considerably advance the quality of goods produced by existing industries that supply major markets.²⁴⁹

The report identified twelve emerging technologies.²⁵⁰ These emerging technologies were divided into four categories: 1) materials (advanced materials and superconductors); 2) electronic and information systems (advanced semiconductor devices, digital imaging technology, high-density data storage, high-performance computing, and optoelectronics); 3) manufacturing systems (artificial intelligence, flexible computer-integrated manufacturing, and sensor technology); and 4) life-sciences applications (biotechnology and medical devices and diagnostics).²⁵¹

The report contained information on areas for future government technological leadership,²⁵² areas for government-industry co-operation,²⁵³ and comparisons with Japan and the European Community.²⁵⁴ The report also focused on areas where opportunities existed to modify the business, educational and governmental environments so as to lower barriers to the effective development and commercialization of emerging technologies.²⁵⁵ The report of-

246. TECHNOLOGY ADMINISTRATION, UNITED STATES DEPARTMENT OF COMMERCE, *EMERGING TECHNOLOGIES: A SURVEY OF TECHNICAL AND ECONOMIC OPPORTUNITIES* (1990).

247. *Id.* at 3.

248. *Id.* at 5.

249. *Id.* at iii.

250. *Id.* at 9. The technologies were: Advanced Materials, Superconductors, Advanced Semiconductor Devices, Digital Imaging Technology, High-Density Data Storage, High-Performance Computing, Optoelectronics, Artificial Intelligence, Flexible Computer-Integrated Manufacturing, Sensor Technology, Biotechnology, and Medical Devices and Diagnostics. *Id.*

251. TECHNOLOGY ADMINISTRATION, *supra* note 246, at 9.

252. *Id.* at xv.

253. *Id.* at xvii-xix.

254. *Id.* at ix-xii.

255. *Id.* at 15-24.

ferred thirteen conclusions with respect to modifying the environment so as to promote emerging technologies:

- (i) lowering the cost of research and market introduction;
- (ii) improving engineering training and education;
- (iii) integrating R&D, design, and manufacturing;
- (iv) improving the quality of products and services;
- (v) improving the technology infrastructure;
- (vi) emphasizing the adoption of international standards;
- (vii) accepting technological innovation from abroad;
- (viii) increasing U.S. industrial cooperation;
- (ix) encouraging protection of intellectual property rights;
- (x) enacting uniform and limited product liability laws;
- (xi) reducing regulatory constraints;
- (xii) removing restrictions on export policy; and
- (xiii) removing restrictive foreign trade practices.²⁵⁶

The DoC report addressed the failure of U.S. industry to capture the majority of benefits from emerging technologies.²⁵⁷ Since there is a strong interest in all sectors of the economy to take action to improve U.S. competitiveness, drafters of the report hoped the document would be used as a tool in pursuit of that goal.²⁵⁸ Specifically, DoC hoped the report would start a dialogue among industry, labor, academia, and government which would lead to concerted actions to improve U.S. competitiveness and strengthen U.S. science and technology options.²⁵⁹

3. National Critical Technologies Panel (NCTP)

The National Science and Technology Policy, Organization, and Priorities Act of 1976 established the Office of Science and Technology Policy within the Executive Branch of the U.S. government.²⁶⁰ The Director of the Office of Science and Technology Policy also serves as the President's personal science advisor.²⁶¹

The National Defense Authorization Act for Fiscal Years 1990 and 1991 established a National Critical Technologies Panel within the Office of Science and Technology Policy.²⁶² The Panel consists of thirteen members who are required to prepare a biennial re-

256. TECHNOLOGY ADMINISTRATION, *supra* note 246, at 15-24.

257. *Id.* at 25.

258. *Id.*

259. *Id.*

260. National Science and Technology Policy, Organization, and Priorities Act of 1976, Pub. L. No. 94-282, § 201, 90 Stat. 459, 463 (1976) (codified at 42 U.S.C. § 6601, 6611).

261. *Id.* at § 204, 42 U.S.C. § 6613.

262. National Defense Authorization Act for Fiscal Years 1990 and 1991, Pub. L. No. 101-189, § 601-5, 103 Stat. at 1511-12 (1989)(codified at 42 U.S.C. § 6681-85).

port.²⁶³ The Director of the Office of Science and Technology Policy appoints nine members, three from the federal government and the remaining six from private industry and higher education.²⁶⁴ The Secretaries of Defense, Energy and Commerce each appoint one member, and the Administrator of the National Aeronautic and Space Administration appoints the remaining member, for a total of thirteen.²⁶⁵ The Act authorizes the Panel to identify product and process technologies, not to exceed thirty, which they consider to be technologies that are essential to the further development of the long term national security and economic prosperity of the U.S.²⁶⁶

In preparing its March, 1991 report, the Panel reviewed recent studies on critical technologies, had briefings with various organizations that have examined the issues, such as the Council on Competitiveness, the National Academy of Engineering, and the National Academy of Sciences, screened a number of technologies against a set of criteria, and placed the selected technologies within a hierarchy which highlighted the interrelationships among them.²⁶⁷ The criteria used for selection by the Panel consisted of national needs, importance/criticality, and market size/diversity.²⁶⁸

The Panel selected twenty-two technologies²⁶⁹ from over one hundred nominees.²⁷⁰ These technologies were divided into six broad areas: materials; manufacturing; information and communications; biotechnology and life sciences; aeronautics and surface transportation; and energy and the environment.²⁷¹ In comparing the critical technologies chosen by the National Critical Technologies Panel with those chosen by the DoC as emerging technologies, all were the same, except the DoC added technologies in the areas

263. *Id.* at § 601-602, 42 U.S.C. § 6681-82.

264. *Id.*

265. *Id.*

266. *Id.* at § 603, 42 U.S.C. § 6683.

267. NATIONAL CRITICAL TECHNOLOGIES PANEL, REPORT OF THE NATIONAL CRITICAL TECHNOLOGIES PANEL 122 (1991).

268. *Id.*

269. *Id.* at 3. The technologies chosen were: Materials Synthesis and Processing, Electronic and Photonic Materials, Ceramics, Composites, High-Performance Metals and Alloys, Flexible Computer Integrated Manufacturing, Intelligent Processing Equipment, Micro-and Nanofabrication, Systems Management Technologies, Software, Microelectronics and Optoelectronics, High-Performance Computing and Networking, High-Definition Imaging and Displays, Sensors and Signal Processing, Data Storage and Peripherals, Computer Simulation and Modeling, Applied Molecular Biology, Medical Technology, Aeronautics, Surface Transportation Technologies, Pollution Minimization, Remediation and Waste Management, and Energy Technologies. *Id.*

270. *Id.* at 2.

271. *Id.*

of aeronautics, surface transportation, and energy and the environment.²⁷²

The Panel's report described each technology and highlighted the reasons for selecting each technology, together with a notation about its current status and emerging international trends.²⁷³

The Panel argued that the success of many firms rests on their ability to bring associated products of generic technology to the market swiftly.²⁷⁴ By showing that it is not necessary for these companies to be the discoverers and developers of the latest innovation, the panel illustrated the importance of integration and short product cycles.²⁷⁵

The Panel concluded by challenging the U.S. to develop and deploy technologies swiftly and strategically, but stressed that our ability to reap benefits will depend upon the quality of our science and mathematics education.²⁷⁶ No advances will be made without a new generation of technologically literate workers.²⁷⁷ The Panel further concluded that technology can be an important contribution to U.S. defense superiority and economic prosperity, but only if the country learns to utilize it more effectively.²⁷⁸

Although the Department of Defense, the Department of Commerce and the National Critical Technologies Panel studies differ, particularly in their scope, there is an extensive overlap among them. The Defense reports concentrated on military advancement and the Commerce study focused on the commercial applications of some of the same technologies. The Panel used both the Defense reports and the Commerce study as source material, but added new areas. All of these reports had the purpose of identifying critical technologies to help in the establishment of policy, but none of these reports had any immediate legal or regulatory significance. The reports merely laid the foundation for the action that now must be taken.

4. Congressional Proposals

Many members of Congress remain dissatisfied with the efforts of the Department of Defense, the Department of Commerce and the Panel. One of the most outspoken is Senator Jeff Bingaman, (D.-

272. NATIONAL CRITICAL TECHNOLOGIES PANEL, *supra* note 267, at 5.

273. *Id.* at 9-116.

274. *Id.* at 1.

275. *Id.*

276. *Id.* at 6.

277. NATIONAL CRITICAL TECHNOLOGIES PANEL, *supra* note 267, at 6.

278. *Id.* at 2.

N.M.) who heads the Senate Defense Industry and Technology Subcommittee. Senator Bingaman criticized the National Critical Technologies Panel report, saying that the level of progress by the Administration had been marginal and that a number of critical technologies had not received any funding.²⁷⁹ He also stressed that after almost three years of list-making it was time to outline what the government should do with respect to each of the technologies to maintain or regain U.S. leadership.²⁸⁰

Senator Bingaman along with Senators Hollings (D.-S.C.), Nunn (D.-Ga.), and Gore (D.-Tenn.) proposed four related bills that would significantly increase and target federal spending to develop generic technology helpful to U.S. industries. They cited the numerous government and industry reports, particularly the Council on Competitiveness' *Gaining New Ground*²⁸¹ as the inspiration for these bills.

The first bill, the National Critical Technologies Act of 1991²⁸² directs the Office of Science and Technology Policy to develop strategic road maps for critical technologies,²⁸³ and authorizes more funding for Defense, Commerce, and other departments that support partnerships to conduct high risk R&D.²⁸⁴ This bill would also create regional critical technology application centers,²⁸⁵ and improve the monitoring of foreign technological advances.²⁸⁶

The second bill, the Advanced Manufacturing Technology Act of 1991²⁸⁷ would increase funding for R&D of manufacturing technology,²⁸⁸ create a manufacturing extension service,²⁸⁹ expand aid for engineering and management education,²⁹⁰ and increase access to foreign technology through international cooperation.²⁹¹ The bill also calls for "coordinated management of federal activities in advanced manufacturing technology, with direct industry input into that planning process."²⁹²

279. See George Leopold, *Congress "Critical" List Lacks Strategy*, DEF. NEWS, April 29, 1991, at 4.

280. *Id.*

281. COUNCIL ON COMPETITIVENESS, *supra* note 14.

282. S. 1327, 102nd Cong., 1st Sess. (1991).

283. *Id.* at § 101.

284. *Id.* at §§ 204, 221-24.

285. *Id.* at § 301.

286. *Id.* at § 404.

287. S. 1328, 102nd Cong., 1st Sess. (1991).

288. *Id.* at § 223.

289. *Id.* at § 302.

290. *Id.* at § 402.

291. *Id.* at § 501.

292. S. 1328, 102nd Cong., 1st Sess. 501 (1991).

The third bill, the Manufacturing Strategy Act of 1991²⁹³ calls for the Commerce Department to act as the leader in development of generic manufacturing technology and require all agencies with R&D budgets over \$50 million to earmark one-half percentage to development of new generic technology, except for Defense, Energy, and the National Science Foundation because these agencies already have well developed existing programs.²⁹⁴ The bill would expand state technology extension programs, create a National Quality Laboratory, and establish a twelve member National Commission on Industrial Modernization.²⁹⁵

The fourth bill, the Federal Technology Strategy Act of 1991²⁹⁶ directs federal agencies to fund private industry projects under the Commerce Department's Advanced Technology Program,²⁹⁷ and requires the Commerce Secretary to submit a report on private investment and commercialization of new technology.²⁹⁸ The Office of Science and Technology Policy would be required to prepare a five year federal technology development plan.²⁹⁹

These bills attempt to further the government's involvement in critical technologies. The thrust of the pending legislation primarily focuses on allocating more funding for R&D and expanding programs within existing agencies or creating new programs and centers in an effort to regain U.S. leadership in technology commercialization of technology.

IV. CONCLUSION

The remaining question is where does the United States go from here? A general consensus exists that the list-making process is at its conclusion and that some type of action must be forthcoming. One of the basic problems turns on coordinating the many plans so that the best proposals of each are implemented by government and industry.

In their effort to improve the commercialization of technology, the federal government can also learn from successful state programs. These programs have focused on linking the state's academic resources with its businesses, thereby improving technology

293. S. 1330, 102nd Cong., 1st Sess. (1991).

294. *Id.* at § 3.

295. *Id.*

296. S. 1329, 102nd Cong., 1st Sess. (1991).

297. *Id.* at § 3.

298. *Id.* at § 4.

299. *Id.* at § 3.

transfer.³⁰⁰

One of the biggest obstacles the state programs have faced is gaining accountability in the face of the prevailing sentiment that government, whether federal or state, is incapable of making intelligent investment decisions. The states which have successful programs, among them Pennsylvania and Ohio, faced an initial struggle since they attempted to challenge the current economic development thinking. As the economies of these rust belt states were rapidly declining, it was necessary to develop new technologies to replace dying industries, such as coal and steel. These state governments realized that it was necessary not only to bring in new industries but also to change existing patterns of investment and ideas about government-industry cooperation.

In examining Pennsylvania's Ben Franklin Partnership, it is evident that the state's goal was a successful transition from an industrial to a post-industrial economy.³⁰¹ The Partnership, named after one of Pennsylvania's greatest entrepreneurs, was designed to help business and academia work together to develop technologies necessary to the state's economy.³⁰² Essentially a matching grant program, its main success has centered on the creation of one of the top intellectual infrastructures in the country.³⁰³ Pennsylvania, as did other states with similar programs, struggled to gain acceptance as it first implemented the program in 1988, but a little less than five years later, its program has been successful in nurturing new high tech companies, modernizing equipment, and creating high tech jobs.³⁰⁴

The danger with all of these programs, either on the state or federal level, is their potential to be politicized.³⁰⁵ As long as the politicians do not interfere and let the science and technology experts decide which technologies should be developed, the programs have a better chance of succeeding.³⁰⁶ However, whether politicization is truly a danger remains to be seen.

The phrase "industrial policy" has incited much debate. However, whether it is called industrial policy, a technology competi-

300. Laurent Belsie, *Make a Better Bottle and People Will Beat a Path*, THE CHRISTIAN SCI. MONITOR, April 26, 1990, at 7..

301. DAVID OSBORNE, LABORATORIES OF DEMOCRACY 45 (1988).

302. *Id.* at 48.

303. *Id.*

304. See Michael Schroeder, *Small Business Has A Friend in Pennsylvania*, BUS. WK., April 6, 1992, at 75, 75.

305. Belsie, *supra* note 300, at 7.

306. *Id.*

tiveness plan, or something else, turning knowledge into new technologies and products which will spur economic growth rests on some type of comprehensive plan. Cutbacks in the large defense budget have provided the opportunity for the federal government to redirect these funds into civilian R&D funding and it is critical to develop a plan.

Contrary to general belief, the federal government has played a key role in the success of certain industries.³⁰⁷ Among these industries are railroads, farming, airlines, and electronics.³⁰⁸ The government did not select these industries as "winning" industries; it simply saw the importance of these industries to the national economy and used the government structure in the form of tax breaks and land grants to aid in their development.³⁰⁹

Generally, agreement exists on the elements needed to create a successful technology growth policy. First, federal spending on civilian R&D needs to be dramatically increased with the money allocated spread over many ideas from basic research to new manufacturing technologies.³¹⁰ Economic studies have documented that the rate of return, both direct and indirect, from R&D can be as high as 50% of the money spent, illustrating the importance of continuing to explore new ideas.³¹¹ That return however, is usually not immediate. Researchers are typically unable to predict the technologies that will be developed from the basic research. Hence government investment in basic research must be encouraged.

The second element in creating a successful technology policy is to provide technical assistance to industry in order to diffuse new technology to manufacturers, particularly the smaller ones.³¹² A major problem faced by American companies is their outdated practices and equipment.³¹³ To help these firms, the federal government needs to increase funding for existing state technology extension centers and create more of these centers to handle the needs of struggling manufacturers who have received little assistance.³¹⁴

Another deteriorating, but important element is public infra-

307. Christopher Farrell & Michael G. Mandel, *Industrial Policy - Call It What You Will, The Nation Needs a Plan to Nurture Growth*, BUS. WK., April 6, 1992, at 70, 70.

308. *Id.*

309. *See id.*

310. *Id.* at 70-72.

311. *Id.* at 72.

312. Farrell & Mandel, *supra* note 307, at 72-73.

313. *Id.* at 73.

314. *Id.*

structure.³¹⁵ In addition to making needed repair of roads, harbors, and bridges, the federal government should build a communications infrastructure to service the needs of "information-intensive" industries.³¹⁶ Presently the federal government has not allocated enough money to help private sector businesses develop an information system that is able to transfer large amounts of data rapidly between research centers and business.³¹⁷ To do this, the government needs to offer incentives to the telecommunications industry to construct high-speed data links which will ensure that data is available to small critical technology companies.³¹⁸

Technology education is another fundamental element in the nurturing of economic growth.³¹⁹ Occupation choices of college graduates affect the growth of the economy. Recent concern has focused on poor performance of students in math and science at the primary and secondary levels, as well as on the insufficient number of graduating scientists and engineers.³²⁰ Increased numbers of scientists and engineers increase the likelihood of new technology and product development, thereby furthering economic growth.³²¹ Many technology innovators will establish their own companies, helping the economy by creating new jobs.³²² The federal government can play a key role by subsidizing the higher education of students pursuing science and engineering degrees and by improving basic education in science and math.³²³

Finally, the federal government should encourage investment in new technologies by making the research and investment tax credits permanent.³²⁴ The private sector should take the initiative by changing the focus from short term profits to long range planning, but the government can improve the climate for investment through the tax incentives.

The Council on Competitiveness's *Gaining New Ground*³²⁵ appears to be the most comprehensive and influential plan. This plan's strength derives from the fact that it addresses every sector of the economy that must be involved, making recommendations with

315. *Id.* at 73-74.

316. *Id.* at 73.

317. Farrell & Mandel, *supra* note 307, at 74.

318. *Id.*

319. *Id.*

320. *Id.*

321. *Id.*

322. Farrell & Mandel, *supra* note 307, at 74.

323. *Id.*

324. *Id.*

325. *See supra* notes 14-16 and accompanying text.

respect to each.³²⁶ What makes this plan the most appealing is its effort to effectuate widespread participation, ensuring that the most important needs of the various sectors are considered in the formulation of the plan. Although every sector, whether it be business, labor, government, or academia, needs to improve, it appears to be the federal government which has the most changes to make.

The federal government could undertake steps to restructure parts of itself based on some of the initiatives implemented by successful U.S. companies. Specifically, the federal government needs to delegate authority, foster teamwork, pursue quality relentlessly, and pay keen attention to its customers. The federal government also needs to have a two year budget so that its many agencies have a greater ability to plan for future spending.³²⁷

Another growing problem is the micromanagement by Congress.³²⁸ Historically, the role of Congress was to help set the overall direction for the nation, but many view Congress today, as meddling in the daily affairs of the executive agencies.³²⁹ A solution lies in improving the consultative process and defusing the increasingly heated partisan debates.³³⁰

A tendency exists in government to ignore problems, including structural ones, that are not seen as urgent. Now, as U.S. industries are faltering, the federal government finds itself unable and unprepared to help. The federal government is not organized efficiently to quickly assemble a qualified group of government agents to develop a technology program to deal with the competitive crisis. The plight of United States critical technologies must be a major national concern.

But creating economic growth is merely the first step. The ultimate success will be achieved when the urban poor are brought into the growth process through education and when they share in the fruits of growth. If our industrial and technological base is to remain strong, knowledge must be passed down through our educational system, providing the foundation for technological leadership in the United States for years to come.

326. See *supra* note 166 and accompanying text.

327. David Kirkpatrick, *It's Simply Not Working*, FORTUNE, November 19, 1990, at 179, 180.

328. *Id.* at 182.

329. *Id.*

330. See *Id.*

LAW OF THE LAN

Diane W. Savage†

Just when we were getting comfortable with the lingo of the PC era — filled with bits, bytes, RAM, ROM, MS-DOS, and PC-DOS — computing has moved into a new age. Local area networks, or LANs, define this new era in which the LAN is the computer, and the vocabulary is a virtual alphabet soup of acronyms such as LAN, WAN, CMIP, SNMP, OSI, TCP/IP, and SNA among others. The growing use of LANs is having a dramatic effect on the manner in which computer software is licensed. Although a basic understanding of LANs is necessary in order to draft an appropriate network software license, it has proved difficult for lawyers to develop an understanding of this complicated and evolving technology. Glossaries of LAN terms are widely available; however, there is a dearth of lay-oriented literature tying these many terms together.

The purpose of this article is to use these terms interactively to define what constitutes a LAN, outline the history of the LAN, describe the hardware “regions” which comprise the LAN, and its software “governance.” Since it has become necessary for LANs to communicate with other LANs, this article will also describe the rudiments of the “international law” of interconnectivity. This article will also address three legal issues which become critical in the context of network licensing because of their economic impact. First, the time honored method of licensing software per CPU is inadequate for networked environments and the growth of networks has given rise to a variety of alternative methods of licensing software for use on LANs. Second, increased reliance on LANs to run mission critical applications, coupled with the rapid growth in computer viruses, has created a new software warranty, known as the computer virus warranty, which is increasingly required by sophisticated software customers. Finally, writing a software program for use on a LAN is more complicated than writing the single user version of the same software, and its proliferation over a LAN dramatically increases the potential economic consequences of an

Copyright © 1993 by Diane W. Savage.

† Ware and Freidenrich, Palo Alto, CA.; J.D., 1974 Georgetown University Law Center; B.A. English, 1971 Emory University.

error, or "bug," in the software. Just as software developers are learning how to develop, install and maintain "network aware" software programs, their lawyers need to learn how to draft "network aware" licenses which responsibly address these issues. The attached appendix will provide examples of "network aware" contract provisions which address these legal issues.

WHAT IS A LAN?

A LAN is a data communications facility that interconnects a number of data transmitting devices, like computers and terminals (these transmitting devices are frequently referred to as "nodes"), and allows for the exchange of data.¹ A LAN is confined to a relatively small area, such as a building or a group of buildings, in contrast to a wide area network (WAN) which may span a large area such as a continent, or a metropolitan area network (MAN) which may span a small city or a town.²

The three key elements of a LAN are its: (1) topology, (2) transmission medium, and (3) access technique.

"Topology" refers to the LAN's physical layout, or the way in which the nodes in a network are connected together. There are three major LAN topologies. These are:

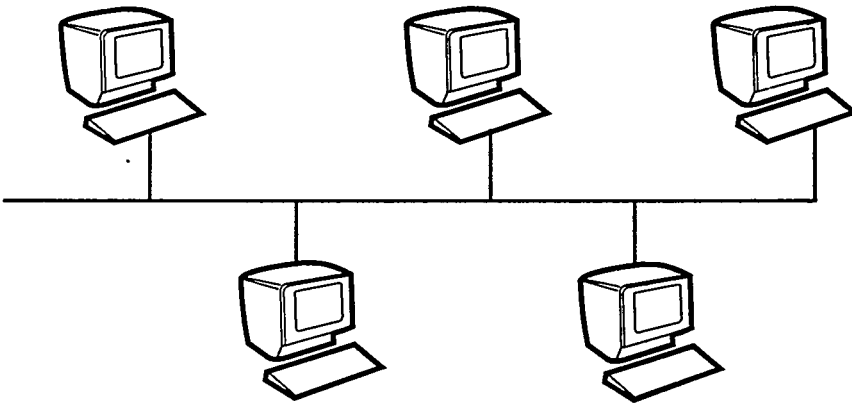
- the bus topology;
- the ring topology; and
- the star topology.

There are also a number of hybrid network topologies which combine features of the above topologies.

In a bus topology, the communications network is a single length of the transmission medium onto which the various nodes are directly connected. This topology is used in traditional data communications networks where the host at one end of the bus communicates with several terminals along its length.

1. The global telephone network is the largest communications network in the world. It serves the needs of voice users well, but is an expensive and inflexible system for data communications. As the proportion of interoffice communication accounted for by data increases vis-a-vis voice, the need for an integrated voice and data service also increases. The change to an integrated service is also outside of the scope of this article, but it involves two approaches. First, the traditional telephone network is evolving into a network known as the Integrated Services Digital Network (ISDN). This standard specifies the interface through which a user may transmit voice and data using telephone switches. Second, integrated services may be offered by an Integrated Service Local Network (ISLN), in which the underlying network is a LAN with interfaces which can carry voice traffic.

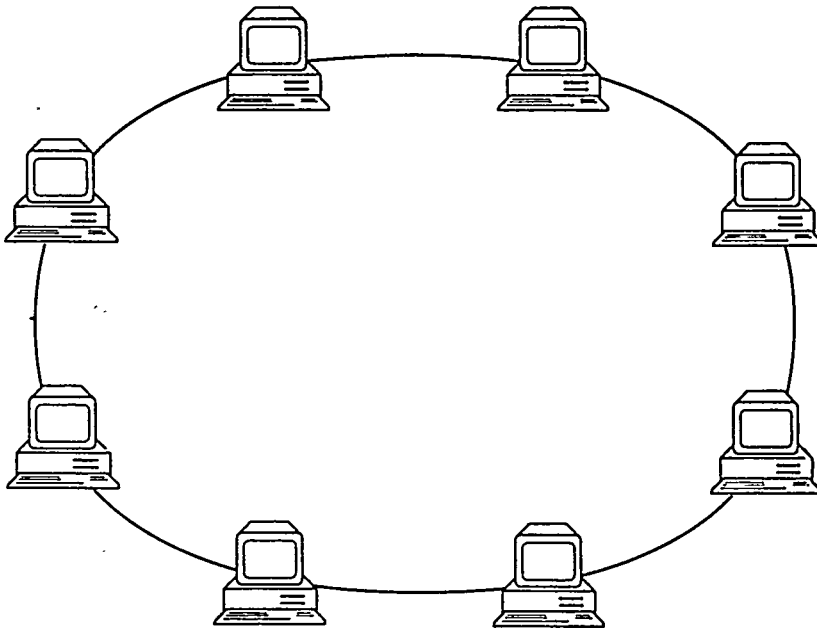
2. This article will not address WANs or MANs, which are also outside its scope.



BUS

In a ring topology, the nodes are connected on a single transmission medium which forms a closed loop. Each node on the LAN acts as a repeater, and data travels through each node. The IBM Token Ring is a star ring or a star-shaped ring and is the most common example of this topology. Because of IBM's Token Ring Network, this topology is expected to gain at least 70% of the local area network market in the next few years.³

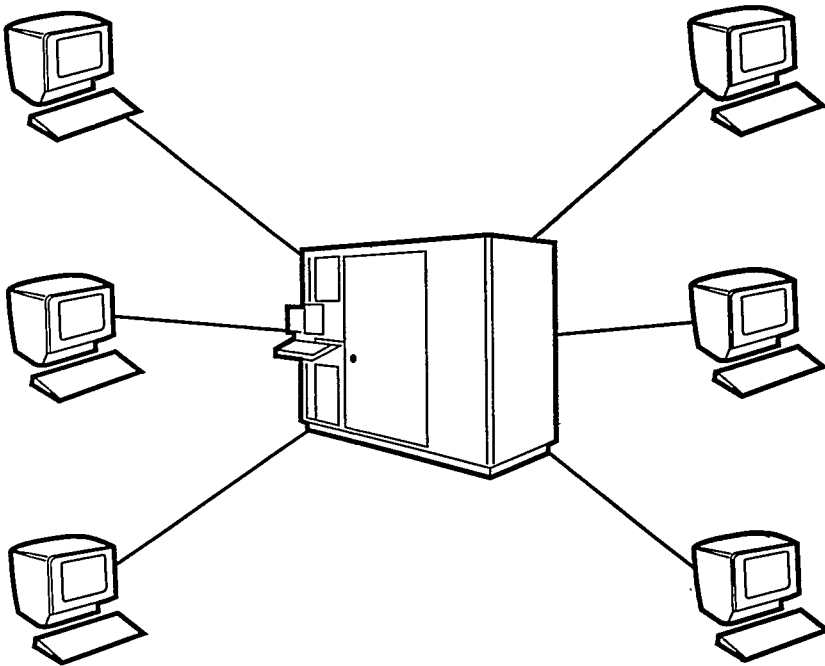
3. STAN SCHATT, UNDERSTANDING LOCAL AREA NETWORKS, 44-45 (1990).



RING

Star topology uses individual data paths from a central hub or concentration point to each node. All data must pass through the hub, just as all telephone calls pass through a central switching station. The pure star topology is not used frequently in data communications, but it is used in IBM 370 installations and in office PBXs.⁴

4. BRENDAN TANGNEY, DONALD O'MAHONY, *LOCAL AREA NETWORKS AND THEIR APPLICATIONS*, 16 (1988).



STAR

LANs must also have a connecting medium of some sort to carry the information from node to node. Many different types of media may be used. The most common forms of transmission media are twisted pair, coaxial cable and optical fibers, although microwave transmission, infrared transmission, and telephone lines may also be used.⁵

Bus and ring topologies require that the transmission medium is shared between a number of nodes. This means that there must be a mechanism for transferring chunks of data from one node to another and another mechanism which ensures that one node's transmission does not interfere with any other node's transmissions. The first mechanism is packet sharing and the second is access control. In packet sharing, data is collected in packets which are launched into the network. The common elements that make up a typical packet are: (1) the start of packet indicator which informs other nodes that a packet is being transmitted; (2) the address of the sender and the receiver; (3) the control field which states the pur-

5. *Id.* at 9.

pose of the packet; (4) the data field which contains the data to be transferred; and (5) the error check field, which allows the network hardware to detect transmission errors.⁶

In access control, the many nodes on a LAN which may wish to transmit data simultaneously are regulated by following a common access method; all nodes observe the same procedures in order to send data. Access control methods can be divided into contention and non-contention methods. In a contention-based access method, a node seizes the opportunity to transmit when the network becomes idle. The most common contention method is Carrier-Sense Multiple Access with Collision Detection (CSMA/CD). With CSMA, the physical layer of a user's workstation generates a carrier-sense signal and listens to detect any other carrier-sense signals from other nodes. If no other signal is detected, the user sends his or her message. However, if two nodes are located far apart, the first node may not detect signals from the second node, with the result that the two nodes commence transmission simultaneously and a data collision occurs. Collision Detection (CD) means that the two nodes listen while they transmit a message. If they detect a data collision, each node waits a different random amount of time before sending the message again.⁷

In a non-contention based access system, a node that wants to transmit data must wait to receive "permission." With one popular non-contention based system called token passing, a free token is passed from one node to another. When a node has taken possession of the token, it has permission to transmit a data packet, and then it passes the token to the next node in the sequence. As Stan Schatt explains in his book *Understanding Local Area Networks*:

To understand how this token approach contrasts sharply with the CSMA/CD bus approach, imagine a public forum on a controversial issue. Under the CSMA/CD method, several people might try to speak simultaneously only to stop speaking when they hear another speaker begin. With dozens of speakers trying to speak yet not wanting to interrupt each other, the process would become chaotic and inefficient. With the token approach, a token would be accepted as a symbol of authority giving a person a right to speak. Whoever held the token would stand and make a speech. When finished, he would pass this symbol of authority to the next person who desired to speak. No one would attempt to speak without physically possessing the token.⁸

6. *Id.* at 27-29.

7. SCHATT, *supra* note 3, at 41.

8. *Id.* at 41-42.

LAN HISTORY

The first computers in the 1940's and 1950's were mainframes which occupied entire buildings. Because they were so expensive, they were available to only a limited number of users. In the 1960's, groups within organizations began to share these high-priced mainframe computers through the use of a primitive network consisting of "dumb" terminals connected with a mainframe computer through telephone lines. Through time-sharing, these various groups within an organization could enjoy the benefits of the mainframe computer without massive capital expenditures, although this time-sharing arrangement could be quite slow.

During the 1970's, minicomputers became available at dramatically reduced prices which enabled work groups to purchase their own computers. This concept of distributing computers throughout an organization by providing groups with their own minicomputers was known as "distributed processing." However, these distributed minicomputers needed to communicate with each other, thus organizations began cabling them together and writing software to enable such communications.

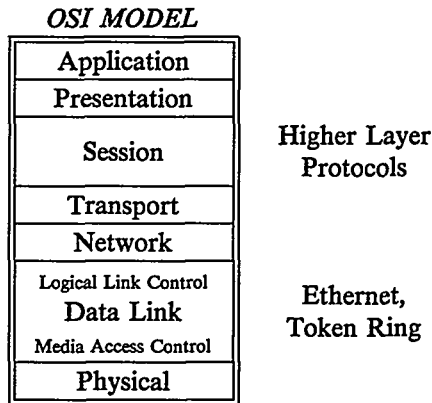
These first experimental local area networks appeared in the 1970's. In 1974, IBM announced its System Network Architecture (SNA) and in 1975 Digital Equipment announced its Digital Network Architecture (DNA). The establishment by major computer manufacturers of their own proprietary network architectures led to a situation where a major manufacturer's computers could communicate easily with each other, but communication among multiple manufacturers' computers was difficult or infeasible. This meant that smaller companies were at the whim of larger manufacturers, who could change their architecture at any time, leading to a demand within the industry for a standard communications architecture.⁹

In 1978, the International Standards Organization (ISO), based in Geneva, Switzerland, released a reference model for computer networking known as the Open Systems Interconnection (OSI) Model.¹⁰ The OSI Model represents a standard approach to communicate information throughout a network, so that a variety

9. TANGNEY & O'MAHONY, *supra* note 4, at 87-88.

10. The OSI, SNA and TCP/IP architectures are the most popular LAN architectures today and can be used on top of any LAN. The Transmission Control Protocol (TCP) and Internal Protocol (IP) issued by the U.S. Department of Defense is currently the most widely available architecture. Like the OSI model, the TCP/IP architecture is layered, but it contains only the following four layers:

of independently developed computer devices can operate on the network. In 1984, ISO released a revised version of the OSI Model which has become an international standard. The OSI Model separates the communications and computing functions provided by LANs into the following seven layers:



The Physical and Data Link layers of the OSI Model establish rules for cabling media, transmission speed, physical topology, and access method of the LAN. The five higher layers provide the methods by which information is reliably transmitted between sending and receiving nodes on LANs and other attached networks, and the way such information is processed and presented to the user. Each layer performs its functions by invoking the services provided by the layers below it, then it returns the results to the invoking layer above. This layering of protocols is a basic principle of standards-based networking.¹¹

<i>Layer</i>	<i>Name</i>
4	Application
3	Transport
2	Internet
1	Network Access

WILLIAM STALLINGS, *THE BUSINESS GUIDE TO LOCAL AREA NETWORKS*, 100-101 (1990).

11. In *Understanding Local Area Networks*, Stan Schatt uses a citizens band radio to illustrate the principle behind the OSI layers. The CB user first presses his send button and announces, "Breaker, breaker" to indicate that he wants to send a message. He then identifies himself with his nickname before asking his friend for her nickname: "This is Happy Hacker, can you read me PC Woman?" After making contact, he asks his friend to switch over to another channel because it is clearer, and his friend acknowledges by replying, "That's 10-4, Happy Hacker." At the physical layer, Happy Hacker pressed certain buttons to broadcast his message. His use of nicknames constituted the second communication layer, established a concrete address for the recipient, and identified himself as the sender. The third layer of communication occurred when he determined the quality of the transmission

In 1980, the Institute of Electrical and Electronic Engineers (IEEE), a U.S. standards making organization, formed a committee known as Project 802, whose task was to work within the scope of the OSI Model to develop a set of standards for local area network topologies and medium access control methods.¹² Project 802 divided the Data Link layer of the OSI Model into two sublayers: a Logical Link Control sublayer (LLC) and a Media Access Control sublayer (MAC). The LLC is concerned with providing a data link service to the higher layers, while the MAC concentrates on providing shared access to the Physical Layer.

Project 802 also produced three IEEE 802 standards of particular interest. The IEEE 802.3 subcommittee established an Ethernet standard for LANs.¹³ It also established the CSMA/CD protocol referred to earlier, which specifies the way that a LAN using bus technology should construct its data packets and send them over the network to avoid collisions. The IEEE 802.4 subcommittee developed Token Bus, a token passing collision prevention standard for a different type of bus network which is frequently used in factory automation. The IEEE 802.5 subcommittee established another standard, Token Ring, to cover networks with ring topologies that use a token to pass information from one workstation to another. Token Ring is the principal PC LAN technology supported by IBM. Ethernet and Token Ring have become the dominant Physical and Data Link layers for LANs.

The growth of the use of PCs and workstations in the 1980's resulted in the need for users to communicate with each other through their common databases and software and to share peripherals. By the late 1980's, the need for LANs was universally accepted. Today, networking is the fastest growing segment of the computer market, according to Doug Gold, an analyst with Inter-

and after switching to an error-free channel, began talking to PC Woman. At each layer PC Woman followed the same rules to respond to Happy Hacker. Similarly, the OSI layers work only when all vendors adhere to them. SCHATT, *supra* note 3, at 34-35.

12. The OSI model originally focused on providing WAN type facilities, but later the scope of the OSI standard was expanded to include LANs and other devices. Since this article is concerned only with LANs, however, it will focus on how the lower Physical and Data Link levels have been standardized in the LAN area by IEEE.

13. During the mid-1970's, Xerox Corporation developed the Ethernet LAN with the announced purpose of creating an industry standard which it would license to third parties. Ethernet was the first major LAN with nonproprietary communications interfaces and protocols, and operates at the Physical and Data Link layers of the OSI Model. By 1980, Intel and Digital Equipment Corporation joined Xerox to announce that their products would be compatible with Ethernet.

national Data Corp. in Framingham, Mass.¹⁴ The shipment value of complex LAN and internetworking products, software, and related services totalled \$4.7 billion in 1989 and is expected to increase to \$11 billion per year by 1993.¹⁵ With this rapid growth of LANs, experts estimate that the percentage of terminals, personal computers, and workstations which are interconnected by LANs will grow from 15% in 1989 to 83% in 1993.¹⁶

COMPONENTS OF THE LAN

LAN Hardware

A LAN is built from the following hardware devices: (1) servers; (2) workstations; (3) transmission media; (4) network interface units (NIUs); and (5) a hub, concentrator, or wiring center. Just as each state has a governor, each workstation has its own operating system software to control local activities. Each country has a chief executive officer, and each LAN has a network operating system, which typically resides in the central file server (the "national capital" of the LAN), to control the activities of the LAN.

Most LANs start out as a homogeneous set of equipment from a single vendor which share a common set of rules, which are frequently referred to as "protocols." As the network grows, however, hardware and software from different vendors using different protocols are added, and the management of the LAN grows more complex. The Network Management System discussed in this article mediates between the protocols of various hardware on the LAN by focusing on standards.

Servers. The network operating system, shared data, and shared applications reside in the server, which is the electronic equivalent of an office filing cabinet. There are two types of servers:

- In client/server LANs, a dedicated "file server" provides a common service to all other workstations, also referred to as "clients," on the LAN. For example, one or more computers might be dedicated to storing files of information for all other computers on the LAN, which can ask these file servers to deliver copies of files on command. Another set of computers might be dedicated to providing laser printing services ("print servers") or access to catalogued information in on-line

14. Stephanie Wilkinson, *Low End LANs Satisfy Users' Simpler Needs*, 11 MIS WEEK, 1990, at 1.

15. *Network Computing Forum to be Launched in January 1991*, PR NEWswire, May 29, 1990.

16. Howard Anderson, *Worth Noting*, NETWORK WORLD, Oct. 14, 1991 at 21, col. 1.

databases ("database servers"). A dedicated server is not available for running programs.¹⁷

- In server-less, or peer-to-peer LANs, each workstation can also be both a client and a "mini-file server" for all other clients on the LAN. Each user can decide which disks or files to make available or publish. Other clients can then access that information across the distributed network. Some believe distributed systems enhance reliability because they theoretically allow multiple repositories for shared data rather than a single main file server as in a client/server LAN.¹⁸

Workstations. Workstations may include IBM computers or compatibles, Apple Macintosh computers, Unix-based and other engineering workstations, and diskless workstations. The workstation is provided with data from the file server, and the actual execution of the application programs occurs at the workstation.

Transmission Media. Transmission media connect the nodes on the LAN.¹⁹ There are three commonly used forms of transmission media:

(1) Twisted pair cabling, the most common form of wiring in data communications consisting of two insulated copper wires arranged in a regular spiral pattern, is the least expensive type of network cabling. Twisted pair comes in unshielded (ordinary telephone wire) and shielded (shielding with metallic braid that reduces interference). Shielded twisted pair provides better performance at lower data rates than unshielded twisted pair, but it is more expensive and more difficult to work with.²⁰

(2) Coaxial cable, composed of a single inner wire conductor surrounded by insulation with an outer jacket of aluminum or copper, is more expensive than twisted pair, but supports both broadband and baseband LANs. Baseband coaxial cable has one channel that carries a single message at a very high speed. Broadband coaxial cable can carry several different signals broadcast at several different frequencies at the same time, and therefore can accommodate integrated voice, data, and video signals. This type of cable is frequently found in homes as a part of cable television.²¹

17. Vinton Cerf, *Networks*, SCIENTIFIC AMERICAN, Sept. 1991, at 72, 74.

18. Ruthann Quindlen, *Why Go Client/Server When You Can Network Peer-to-Peer?*, April 15, 1991, INFOWORLD, at 90.

19. An alternative to transmitting the information over cables is to transmit it using infrared or microwave radiation. Although it is impractical in the usual office situation, it can be useful for communicating between buildings. TANGNEY & O'MAHONY, *supra* note 4, at 12-13.

20. STALLINGS, *supra* note 10, at 46.

21. SCHATT, *supra* note 3, at 26-27.

(3) Optical fiber, consisting of a pure glass cable drawn into a very thin fiber to form a core, is the most expensive type of network cabling, based on media and installation cost. Optical fiber uses analog signaling to carry data in the form of modulated light beams. Optical fiber is used for very high speed and/or high capacity data communications needs. One type of network that uses fiber optics is Fiber Distributed Data Interface (FDDI).²²

Network Interface Units. Network Interface Units (NIUs) are the cards that plug into a workstation or server to connect it to the transmission medium. The NIU contains logic for accessing the LAN and for sending and receiving data packets on the LAN.²³ The main task of the NIU is to form these data packets from the workstation and transmit them onto the transmission medium. The NIU also receives data packets from the transmission medium and translates them into bytes which the workstations can understand.

The Hub, Concentrator or Wiring Center. Each workstation on a network needs access to the file server. However, it is usually not possible to have every workstation directly attached to the file server. To accommodate multiple workstations, a hub or central wiring center may be used, although certain network architectures (like ring topology) do not require hubs.²⁴

LAN Software

The Workstation Operating System. The operating system for each workstation is loaded at the workstation and acts as the "governor" for the workstation, controlling the execution of other software on the workstation. The workstation operating system also includes, or works in conjunction with, software created by the network operating system which is loaded on the workstation. Each network operating system has a different name for this piece of software, which is sometimes referred to as a "requestor" or "redirector," and which determines whether the requests made by the workstation are for local processing or network processing. If the request is one for local processing, like copying of local files or formatting of local media, it is serviced by the workstation operating system. If the request is one for network processing, it is serviced by the network operating system. The workstation operating system is essential for the workstation to operate, even if it is not a part of a network. The workstation operating system conceptually

22. STALLINGS, *supra* note 10, at 48.

23. *Id.* at 6.

24. GREG NUNEMACHER, LAN PRIMER, 59 (1990).

resides in the Presentation Layer of the OSI Model.²⁵

The most popular workstation operating system today is MS-DOS from Microsoft, which is found on IBM PCs and compatibles. Because DOS was originally designed as a single user operating system, most PC LAN implementations have been forced to take a three-tiered approach to network governance consisting of DOS, NIUs and a separate network operating system. However, IBM's newer OS/2 operating system is an integrated operating system which includes both workstation and network operating system components. As a result, OS/2 eliminates the need for a separate network operating system.

The Network Operating System. The network operating system controls all network activity. The network operating system manages access to the data on the hard disks of the file server, handles security of the data on the file server's storage devices, communicates between the user and the network, accesses network services, accesses shared printers and other servers, and accesses shared outside services such as gateways and bridges. The most common network operating system on the market today is NetWare from Novell.²⁶ NetWare offers a fairly complete suite of network protocols, and there are more products available for NetWare than any other LAN operating system.²⁷ The network operating system conceptually operates at the Application Layer of the OSI Model.

Network Applications Software. The challenge for the 1990's is for software companies to develop a new type of LAN applications software. The packaged software of the 1980's, primarily designed for use on standalone computers, is inadequate because it cannot anticipate all of the combinations of hardware and software on which an application must operate in a network and because it is not designed to take full advantage of the communications features of the network. According to Patricia Seybold, president of Office Computing Group, a Boston consulting firm, new network application software is "where all the action is, and where it's going to be for the next 10 years."²⁸

The development of network applications software requires a

25. *Id.* at 23-24.

26. Netware has a 63% share of the network operating system market. Sandra Atchison, Evan I. Schwartz, *Can LAN Lord Novell Extend its Territory?* BUSINESS WEEK, September 2, 1991, at 78.

27. Paul Korzeniowski, *Everything to Everything in a Network of Networks*, SOFTWARE MAGAZINE, June 1990, at 69.

28. Richard Brandt, *Software: It's A New Game*, BUSINESS WEEK, June 4, 1990, at 102, 105.

radical change in the software which software suppliers develop, as well as the way they market, distribute and support software. Although most standalone software today is "networkable" (which means that it is able to function on a network without additional changes), there is an increasing demand for "network aware" software — software which is designed from the ground up to run efficiently in a networked environment. Both networkable and network aware software generally include file locking functions,²⁹ and may include a license manager utility to restrict software usage. However, network aware versions generally include additional features which make them more adept at handling the hardware and software configurations of multiple users, such as record-locking,³⁰ customized start-up files which let users call the application from a server using appropriate device drivers for their particular workstation configuration, file transfer facilities, and facilities to access other remote peripherals. Network aware software frequently takes the form of groupware, which includes office automation type functions like group calendaring, project management, voice messaging, e-mail, and call tracking.³¹

Writing network aware software is an order of magnitude more complicated than creating the single user version of the same program.³² An example of a problem conversion of a single user software system to a network specific version was Ashton-Tate's Multiuser dBASE II, which Ashton-Tate withdrew from the market. According to Ashton-Tate's public relations manager, "it could have corrupted some data," although "it was not a major bug" that stopped shipment of the network specific version.³³ More recently, DSC Communications Corporation reported that three binary digits set incorrectly in minor software updates to its call-routing switches knocked out telephone service to ten million people in

29. A "file lock" provides the ability to lock a file so that only one user may use it at a time.

30. A "record lock" provides the ability to lock a record so that several users can share the same file at one time, but cannot share the same record within a file.

31. SOFTWARE PUBLISHERS ASSOCIATION, NETWORK LICENSE SURVEY, 1-2 (1990).

32. "People who have been around the computer track a few times think all LAN products should carry a label: WARNING! Use of this product could be hazardous and possibly fatal to your business health! Like alcohol, chocolate and television, networks carry a large potential for abuse. Your level of involvement must be balanced against the wisdom of keeping a safe distance away from any volatile, unstable substance. Think of LANs as nitroglycerine: this would give you just the right amount of respect for their exposure potential." John Hawkins, *Networks: the creatures with two heads; the perils of being a network consultant*, DATA BASED ADVISOR, November 1989, at 12.

33. Keith Yocum, *Software Shortage Has LAN Industry Tied Up*, PC WEEK, April 2, 1985, at 52.

five states and the District of Columbia. Congressmen and witnesses testifying at a hearing on the outages stressed that telephone companies should have better contingency plans for dealing with disruptions "that are certain to occur as network software becomes more complex."³⁴

Network aware software also involves substantially more support from the vendor to customize the software for the users' needs and to install the software on the network. As a result, Patricia Seybold estimates that for each dollar which a company spends on software for networks, it spends five dollars on consulting systems, integration and custom programming.³⁵ An example of this is Lotus Notes, a groupware program that runs on PCs and enables workers on a network to communicate more effectively. Notes customers who pay \$62,500 receive a programming system, 200 copies of Notes, five days of consulting and six months of technical support.³⁶

This move to consulting is something of a "back to the future" strategy. Thirty years ago, computer companies sent teams of programmers to their customer's sites to develop custom software for their new mainframe computers. This changed in the 1980s, when independent software companies emerged to supply prepackaged software for use on PCs. In the new networking era, software companies are discovering that demand for consulting and custom software development is growing rapidly as corporate customers begin to move large applications from mainframes to PC-based LANs. For example in 1991, one year after Microsoft launched its consulting unit, it had 200 consultants in seven countries working for over 150 clients to meet their needs for consulting and custom software development.³⁷

The Network Management System

The Network Management System consists of hardware and software additions which are implemented among the network components described above. The Network Management System views the LAN as a unified architecture, with addresses and labels assigned to each node, and the specific attributes of each node known

34. Gary H. Anthes, *Phone Outages Traced to Software Updates*, COMPUTERWORLD, July 15, 1991, at 4.

35. Brandt, *supra* note 28, at 105.

36. *Id.* at 104.

37. Stacey Peterson and Amy Cortese, *Microsoft Smooths Partners' Feathers*, SYSTEMS AND NETWORK INTEGRATION, Dec. 2, 1991, at 76.

to the system. ISO has suggested the following five key areas of network management:

(1) *Fault Management.* When fault occurs, the Network Management System should be able to determine the location of the fault, isolate the rest of the network from the failure, modify the network to minimize the impact of operation without the failed components and repair or replace a failed component to restore the network to its initial state.

(2) *Accounting Management:* The Network Management System should be able to track the use of network resources by user and user class for planning network growth, as well as for internal accounting purposes, to determine whether a user or group is abusing access privileges or whether users are making inefficient use of the network.

(3) *Configuration and Name Management.* The Network Management System should control initializing a network and shutting down part or all of the network, as well as maintaining, adding and updating the relationship among its components and the status of components during network operation.

(4) *Performance Management.* The Network Management System should be capable of tracking activities on the network and enabling performance management to make adjustments to improve network performance (e.g., by controlling capacity use level, excessive traffic and response time).

(5) *Security Management.* The Network Management System should monitor and control access to the network and to all or part of the network management information from network nodes.³⁸

The Network Management System is typically comprised of one or more Network Control Hosts and associated software commonly known as the Network Control Center and the Network Management Entities.

Network Management Hardware. In today's world, each vendor's equipment may be managed by a different workstation (commonly called an "element manager"). However, in an Integrated Network Management System (INMS) that manages many types of LAN to WAN connections and devices, one or more workstations are designated as the Network Control Host.

Network Control Center. The Network Control Center is a collection of software which resides on the Network Control Host.

38. STALLINGS, *supra* note 10, at 251-255.

The Network Control Center includes an operator interface so that the designated administrator can manage the network. The Network Control Center responds to user requests concerning the LAN by displaying information and issuing requests for information to Network Management Entities, described below. This communication is carried out with an Application Layer network management protocol that uses the communications architecture in the same fashion as any other distributed application.³⁹

Network Management Entities. Each network node contains a collection of software known as the Network Management Entity, which is dedicated to certain network management tasks. The Network Management Entity collects and stores statistics on network related activities, and responds to requests and commands from the Network Control Center.

Because network management software relies on the host operating system and communications architecture, most Network Management Systems today are designed for use on a single vendor's equipment. However, vendors of Network Management Systems are focusing on two protocols that are emerging as open network management standards to permit these systems to manage multivendor networks — TCP/IP based simple network management protocol (SNMP), which is maintained by the Internet Activities Board, and common management information protocol (CMIP), which is based on standards set by ISO. These protocols provide a common format for network devices such as bridges, routers, concentrators and modems to communicate management data via an "agent" to the Network Control Host. In addition, CMIP allows communications among different Network Management Systems. The move toward multivendor support will provide administrators of large heterogeneous networks with critical long term advantages. For example, network administrators will be able to monitor and control multivendor networks from a single point in the network.

All Network Management Systems handle multiple protocols in the same way. SNMP management information bases (MIBs), CMIP objects and attributes, and the proprietary definitions of managed objects in the network are grouped together in the Network Management System's memory according to the types of devices that the system handles. Translation routines, which match the object definitions with what they manage in the network, are

39. *Id.* at 259-262.

handled in one of three ways. The first approach is to handle this translation on the Network Management System, whether it is an Integrated Network Management System (INMS) that manages many types of LAN to WAN connections and devices, or an element manager that handles just one kind of device. The second approach, used by IBM and AT&T, is to use an application program interface (API) to handle conversions between standard and proprietary protocols. The API is provided to third party vendors, including other network management vendors and companies that manufacture element management stations, which can then map their proprietary routines to the API.⁴⁰ The third approach is to put the burden of protocol translation on the applications that run on the managed devices in the network. Using this approach, each managed device contains a software protocol gateway that converts incoming messages from the Network Control Center to its own protocol.⁴¹

INTERCONNECTIVITY: THE INTERNATIONAL LAW OF LANS

As LANs become more prevalent, the need for LANs to communicate with each other becomes more pronounced. The underlying objective of interoperable products is to facilitate a union of a number of LANs through the establishment of protocols which govern the exchange of information among participating LANs.⁴² To carry out this objective, four major components are used: repeaters, bridges, routers, and gateways (or backbones). These products perform tasks to achieve compatibility among LANs at different levels of the OSI Model as follows:

40. Mary Jander, *Net Management Enters the Multivendor Era*, DATA COMMUNICATIONS, Feb. 1991, at 49-51.

41. *Id.* at 51.

42. Richard Pastore used a similar metaphor to point out the need for such protocols: "An archipelago of isolated islands, each with its own native language and customs. It sounds idyllic — unless you're talking about islands of data distributed across several local-area networks. Then the image becomes a Bermuda triangle of lost data integrity, data inconsistency and incompatible security protocols." Richard Pastore, *LAN Ho! Navigating Downsized Data*, COMPUTERWORLD, June 4, 1990, at 67.

<i>Device</i>	<i>OSI Model Layer</i>
Gateway/Backbone	Level 7 Application Services
Gateway/Backbone	Level 6 Presentation
Gateway/Backbone	Level 5 Session Control
Gateway/Backbone	Level 4 Transport
Router	Level 3 Network
Bridge	Level 2 Data Link
Repeater	Level 1 Physical ⁴³

Repeaters. Although repeaters are categorized as internetworking devices, they actually connect segments of the same network to form an extended network. In other words, repeaters are used when a LAN wants to expand its own boundaries rather than to govern the relationships between two LANs. A repeater is not used to interconnect different networks: it is used to "repeat" the electrical signal between cable segments and physically extend a single network.⁴⁴ The repeater functions at the lowest level of the OSI Model, the Physical Layer, and its sole function is to extend the maximum length that a signal can travel, thereby extending the physical size of the network.

Bridges. Bridges connect two similar LANs that use identical protocols. Bridges are divided into those that connect LANs in the same site (local bridges) and those that make use of telecommunications facilities to interconnect LANs at different sites (remote bridges).⁴⁵ The bridge picks up data packets from one LAN that are intended for a destination on another LAN and passes these packets on. Each time the bridge transfers packets between networks, it also acts as a repeater to regenerate the signals. The bridge does not modify the packet or add anything to it. The bridge is more intelligent than a repeater in that it can look at the header of a data packet and determine to which of the two networks the packet belongs. Bridges operate at level two of the OSI Model, the Data Link Layer, so layers three and above must be identical in the two systems for successful communications in a bridge.⁴⁶

Routers. Routers are used to interconnect networks that may or may not be similar. The router operates at level three of the OSI Model, the Network Layer, sometimes known as the internet proto-

43. Michael Grimshaw, *LAN Interconnections Technology*, TELECOMMUNICATIONS, February 1991, at 25.

44. Kurt Vandersluis, Paul Kent, MacUser Labs Staff, *Building a Better Network with EtherTalk-to-LocalTalk Routers*, MACUSER, April 1991, at 156, 158.

45. STALLINGS, *supra* note 10, at 187.

46. *Id.* at 187-191.

col. This internet protocol is present in each router and in each host on the network. In addition, as with the bridge, each host must have compatible protocols at layers four and above in order to communicate successfully.⁴⁷

Gateways and Backbones. Gateways are the most complex interconnectivity devices. The gateway is used to connect computers that use different communications architectures. The gateway functions on all seven layers of the OSI Model so it can be used to connect OSI-based products with proprietary products, like a LAN using IBM's SNA architecture. The gateway maps from an application on one computer to an application that is similar in function, but which differs in detail, on another computer.⁴⁸

Networks with different communication architectures can also be connected via a backbone network. A backbone network is a control network to which other LANs are attached. Fiber optics are usually used for backbone networks because backbones require a larger bandwidth and need to be able to transmit across long distances. The LANs are attached to the backbone network via bridges, routers, or gateways, depending on the architectures of the LANs and of the backbone.⁴⁹

"NETWORK AWARE" LICENSE ISSUES

Methods of Licensing Software For Use on LANs

Software companies are changing the way they do business because computer networks are changing the way companies handle information. The use of mainframes in the 1960's did not provide individual workers with the tools they needed to do their jobs. PCs, on the other hand, provided job-specific tools, but did not let workers share information or work collaboratively with each other. Groupware on LANs is allowing workers to coordinate their activities through e-mail and office automation-type functions like voice messaging, project management, group calendaring and call tracking.

The increasing use of software on LANs has resulted in a demand by users for a consistent, common way to license, distribute and administer applications software across a network. The time-honored licensing practices of licensing shrinkwrapped software either per processor or via a by-site license are inadequate for

47. *Id.* at 207.

48. *Id.* at 210.

49. NUNEMACHER, *supra* note 24, at 142-144.

networked environments where applications are shared by users on heterogeneous computers and where the network itself is constantly changing size and configuration.⁵⁰

Software companies, on the other hand, are concerned that LANs present a real threat to their economic survival. When a network administrator buys a single-use copy of a software program and lets ten people on the network access that program simultaneously, the software company loses a lot of money. As a result, software companies which were forced by the marketplace to drop copy protection schemes during the mid-1980's are now implementing such schemes again in the context of LAN licensing.

Rather than balking at such schemes, sophisticated computer users are asking for them. The network administrators in a recent Software Publishers Survey unanimously favored lock-out systems. The Survey reported that:

One administrator complained adamantly about publishers that do not provide this utility in network versions of software: "They provide a LAN edition and then basically say 'you control it,' without giving you the tools to do it. It's asking for problems."⁵¹

The growth in LANs has resulted in a plethora of license approaches. "We get a lot of calls from network administrators who have some problem where they're running 10 different packages and they are licensed in all sorts of different ways," says Ann Stephens, research director for the Software Publishers Association. "It can make for all sorts of headaches as far as controls go."⁵² The following example illustrates the problem.

A company with 200 employees, 100 workstations and three file servers, loads an application program on all the three file servers. No more than 80 employees ever use the program, and there are never more than 60 users at one time. However, the amount charged for such use will vary based on the license model which the software supplier has adopted.

Per CPU licensing - the customer pays for 100 licenses.

Per User licensing - the customer pays for 80 licenses.

Server-based licensing - the customer pays for three server licenses.

50. Jeff Moad, *IS Shops Push for a Consistent, Networked Software Plan*, DATAMATION, Feb. 15, 1988, at 17.

51. SOFTWARE PUBLISHERS ASSOCIATION, *supra* note 31, at 4.

52. Sharon Fisher, *The Licensing Game*, LAN TIMES, April 1, 1991, at 65.

Site licensing - the customer pays a negotiated fee for unlimited use within a defined site.

Concurrent Use licensing - the customer pays for 60 licenses.

1. *Per CPU licensing.* Some software suppliers license their software for use on a single CPU.⁵³ This license scheme is easier for network administrators to manage than per user licensing. However, it may be uneconomic for users if some workstations require only occasional access to the software program. In addition, users may have files on unlicensed CPUs which require complicated file transfers to use with the software programs on the licensed CPUs.

Some software suppliers enforce their per CPU licensing approach with node-locking. A node-locked license ties an application to a specific machine by way of special hardware or software so that the software will execute only on that machine.⁵⁴ This is typically accomplished via a hardware serialization scheme. In hardware serialization, when the user installs a software program on a CPU, the program copies the unique serial number of the CPU into itself and thereafter cannot be run on any hardware containing a different serial number. Node-locking can create problems when the licensed node is out of service since the CPU-locked software cannot be easily moved to a back-up CPU.

These problems can be avoided with a token-based scheme or an RS232 25-pin connector. In a token-based scheme, the software program cannot be run unless the original software diskette is inserted in the disk drive of the CPU. This mechanism ensures that the program can only be run in one CPU at a time, but does not "lock" the program to a single designated CPU. Alternatively, a hardware serialization scheme can be used to lock use of a software program to a particular RS232 25-pin connector, which the user can nevertheless move from one CPU to another. Other software suppliers put a serial number in each copy of the software, which

53. The Software Publishers Survey reported that WordPerfect licensed its software on a single machine. However, a more recent publication indicates that WordPerfect may have adopted a compromise between the per CPU and concurrent use licensing approaches. INFOWORLD reported in October 1991, that WordPerfect "took an unexpected tack" when it announced at Comdex that it would offer concurrent use licensing for its PC programs; however, if users choose to copy the program to their local hard disk, they must purchase an additional license. "We ask users to find two numbers — the maximum number of users who would use it concurrently and the number of computers that have it on their local disks — and then license the higher number," reported Pete Peterson, Executive Vice President of WordPerfect. Louise Fickel, *WordPerfect Shifts to Concurrent-Use Licensing*, INFOWORLD, Oct. 28, 1991, at 1.

54. M. Olsen, P. Levine, *Concurrent Access Licensing: Restricting the Number of Application Users*, UNIX REVIEW, Sept. 1988, at 67.

instructs the software to check the network to be sure that software with the same serial number is not being used elsewhere. Although this type of serialization allows the software program to be used in alternate or back-up CPUs, it still requires unnecessary use of multiple copies of the program on a LAN. It also does not provide the network administrator with an easy way to find out which user is running a duplicate copy of the software and makes software upgrades difficult because the administrator must install the upgrade with the same serial number on the same computer as the original software.⁵⁵

Increasingly, per CPU licenses are implemented on LANs through "LAN packs." LAN packs are typically offered in groups of three, five, or more. For example, a user licenses one copy of software for the server, and then pays an additional amount for each additional copy, or alternatively for the right to copy and use the software for each additional group, or "pack," of CPUs. The price per unit typically decreases as the size of the pack increases, since the software vendor has no costs for duplicating disks or documentation. Some users dislike license packs because they may be forced to buy more than they need. Jeff Chimbly, LAN services administrator for Farm Bureau Insurance Companies states, "We like to buy [additional copies] in increments of one. Paradox offers increments of five. If you have three nodes, then you have two extra Paradoxes lying around, and that seems like kind of a rip-off."⁵⁶

2. *Per User Licensing.* A small number of software suppliers license their programs to an individual, who may be designated by name or by position. This type of license can be enforced on the network through software control or passwords which allow only preauthorized users to access a program. However, this type of software control or password scheme does not work if the user also needs access to the software on a computer at home which is not a part of the network.

Licensing software to an individual makes it clear who is allowed to run the software, but raises other questions. For example, can the licensed user run the software on a second machine without physically removing it from the first machine, and what happens to the license when the licensed user leaves the company or no longer requires access to the software?⁵⁷ Microsoft Corporation has

55. Sharon Fisher, *Licensing Multiuser Software Varies by Vendor*, INFOWORLD, Jan. 22, 1990, at S8.

56. *Id.* at S12.

57. Fisher, *supra* note 52, at 65.

adopted a unique approach to the first of these issues: the "80/20 split policy." If a Microsoft program is licensed to an individual at his place of work, he or she can use the software (without unloading from the primary machine) for up to 20% of the time for use at home or on a portable computer. Similarly, if the program is licensed to an individual at home, he or she can use it at work for up to 20% of the time.⁵⁸

A LAN alternative to the per user approach is the approach adopted by Swiss Bank, which purchases a license for every single user on the network, including the possibility of simultaneous use. This approach offers an administratively simple way to determine the number of software licenses required at a given network installation, but may be expensive if every network user does not actually require access to the same software products.⁵⁹

3. *Server-Based Licensing.* Server-based licensing represents another approach to network licensing. Server-based licenses allow unlimited use of a program on a specific number of servers. In server-based licensing, the "server" portion of an application resides in the server and the "client" portion of the application resides on each node. As a practical matter, the server and client portions of the application could be licensed separately; however, the software supplier typically elects to license the server portion of the program to one or more servers and to permit an unlimited number of copies of the client portion of the program to be made. One of the advantages of server-based licensing is that it is easy to manage. However, since server-based licenses provide for unlimited use of a program on a network with a specified number of servers, they can be too expensive if a company has a need to use a program on only a limited basis. As a result, server-based licensing is more appropriate for programs that are inherently LAN-based, such as electronic mail and other groupware.

A disadvantage of server-based licensing for the software supplier is that server licensing could reduce potential revenue for such programs, since the only limit to the number of users is the speed

58. SOFTWARE PUBLISHERS ASSOCIATION, *supra* note 31, at 11. According to a recent article, however, Microsoft may be moving to a concurrent licensing approach. Computer World reported that Mike Maples, Vice President of Applications at Microsoft, announced at Comdex in May 1991, that Microsoft had changed its software licensing policy to concurrent use licensing, effective immediately. It is unclear whether this supersedes or supplements Microsoft's earlier, per user approach. Jim Nash, *Microsoft Eases LAN Licensing Policy*, COMPUTER WORLD, June 3, 1991, at 136.

59. John McMullen, *What's Wrong With Network Licensing*, DATAMATION, Oct. 1, 1990, at 43.

and capacity of the system, which is constantly increasing due to technology advances. As a result, from the suppliers' viewpoint, server-based licenses make the most sense for disk-intensive software, such as multi-user database managers that limit the number of people who can effectively use a file server because they require more frequent interactions between the local workstations and the database stored on the file server.

4. *Site Licensing.* Some companies negotiate site licenses for large customer installations on a case-by-case basis. The term "site licensing" has no accepted, consistently applied meaning, and site license terms may therefore vary dramatically. A site license can permit use of software on an unlimited number of computers at one or more geographic sites, it can permit business use by employees of the licensee on an unlimited number of computers at any location, or it can permit use of software on a specified number of computers at one or more geographic sites or at any location. A site license can permit reproduction of the software and/or documentation by the licensee or it can require that the licensee obtain copies of the software and/or documentation from the software supplier. A site license may also enable a licensee to distribute an upgrade by making it available to all nodes via the server rather than requiring the licensee to collect the individual copies of the old version and distribute individual copies of the upgrade, which would be required in a per CPU-based license.

Under a site licensing model, a user typically pays a flat fee for the right to make copies of a software program for use at a particular geographic site.⁶⁰ This fee will probably be too expensive if a user requires only limited access to a program. As with server licensing, site licensing is therefore more appropriate for programs that are inherently LAN-based. However, it may be the least popular approach for software suppliers who will be concerned about continuing to use site licenses in network environments because they have no way of knowing how large a network will grow and therefore are required to guess at how much to charge for the site license.⁶¹

60. For example, Lotus Development Corporation licenses Notes groupware that runs on OS/2 in the server system and on Microsoft's Presentation Manager and Windows on the client workstation, to sites of at least 200 users at a cost of \$62,500. Kelly Jackson, *Lotus Buys E-Mail*, COMMUNICATIONS WEEK, Feb. 18, 1991, at 2.

61. Mort Rosenthal, President of Corporate Software, Inc., a reseller in Canton, Mass., said a software company's size and revenues are factors in site licensing. "The only vendors [selling on an unlimited use license] are the ones desperate for cash," he said, emphasizing the lack of large suppliers who will site license. "This is because it cuts off the revenue stream

As an extra-legal aid to enforcement of a site license, the software supplier may provide the site licensee with a master diskette which contains an internal counter to limit the number of copies made according to the terms of the site license. A similar type of control includes a requirement that the customer copy protect all copies distributed internally, even if the master copy is not copy protected. Where there is no technical limitation on the number of copies, the software supplier may negotiate a contractual right to audit the site licensee's use to ensure that it does not exceed the scope of the site license. To assist in such a situation, the supplier may require the customer to obtain official labels from the supplier for each copy so that the number of copies reproduced never exceeds the number of labels ordered from the publisher.

5. *Concurrent Use Licensing.* Most major software suppliers have adopted the concurrent use licensing approach for network software.⁶² Concurrent use licensing requires users to pay only for the maximum number of simultaneous uses of the software program on a network. If license manager software is used to enforce concurrent use licensing, users "check out" the software, up to the licensed number of simultaneous uses. When they are finished, they "return" the software, making it available to other users. The benefits of concurrent use licensing include greater flexibility in software use for end users and simplified software distribution for the software supplier since the user can typically increase the number of permitted uses by placing a phone call to the software supplier. It also streamlines distribution of updates, since installation of the update on the file server is typically all that is required to update all users on the network. Finally, it is cheaper than per CPU or per user licensing since the number of concurrent use licenses required will typically be less than the total number of CPUs or users which require access to the program.

One of the disadvantages of concurrent use licensing is that it is virtually impossible to administer without some type of metering system. The most common method today appears to be license manager software, which allows only a specified number of users

from the customer once the software is purchased. The only ones who are doing it this way are small vendors and Computer Associates. The only reason to sell site licenses is if you don't think you're going to make any other money from the customer or if you're not the preferred vendor." Scott Kramer, *Vendors, Users, Face Off In Site License Debate*, COMPUTERWORLD, June 3, 1991, at 45.

62. SOFTWARE PUBLISHERS ASSOCIATION, *supra* note 31.

simultaneous access to the software (capacity licensing).⁶³ Some of these products will allow only a preset number of users to use a program at one time. Other products only audit and report, but do not lock users out. These reports show when the demand exceeds legal supply so that the network administrator can correct the situation by purchasing additional licenses.

Although license manager software utilities are commonly used in the Unix world, many software developers say they are not able to develop an effective license manager program for their applications when running under Windows. This is because in the Windows multitasking environment, an application is counted as being in use when an user retrieves an application and makes it an icon on the screen even if the application is actually not being used.⁶⁴

Some network operating systems include their own license manager software, but each application software program on the LAN must conform to the application programming interface (API) for the license manager software in order to be managed by it. In contrast, the application software program may contain license manager software, but this means that different application programs on the network will use different metering schemes. Network administrators generally want the ability to choose between use of the network license manager software and the application specific metering software.⁶⁵ It is therefore desirable if each application program with license manager software checks to see if the network operating system has its own license manager program or if a third party license manager program has been installed. If either exists, the network administrator should be able to turn off the redundant application-specific metering software.

Because of the difficulty of administering a network with multiple license manager software programs, the Microcomputer Managers Association in Warren, N.J., recently published a white paper on network software licensing issues which included a call for an

63. Cheryl Currid, *Windows 3.0 - Designed With Networks In Mind*, PC WEEK, May 22, 1990, at S44.

64. Jim Nash, *Users Seek Vendor Pact on Metering Utility*, COMPUTERWORLD, Nov. 11, 1991, at 1.

65. An example of a network system is the Flexlm system from Highland Software. Software suppliers acquire a logical lock from Highland Software and implement the lock on their source code. Flexlm manages the licenses or "keys." The user licenses Flexlm software along with a rack of key hooks on which to store the license keys. The user buys an application from a software supplier, with a set of keys that define the maximum concurrent usage of the application. A user at any node can access the software as long as a key is available. If additional hooks or keys are needed, the user can purchase them from the software supplier. *Flexible License Manager Technical Overview*, HIGHLAND SOFTWARE, April 1990.

API which would be common to all network operating systems. Without such a common API, software developers must build multiple metering hooks from their applications into each network operating system's metering program.

After surveying the various license options and the available license manager software, the MMA concluded:

While it is convenient to have the metering software provided with the application, there are problems associated with this approach. First, each application would have its own interface for its metering software. Second, there would be multiple programs which might require that administrative information be entered. It makes much more sense to have a single package provide the metering for all application software on the network.

If we concede this point, however, software publishers have a problem: with which of the metering packages on the market should they be compatible? To overcome this problem, the metering should be done by the NOS ["Network Operating System"]. Users have been clamoring for more and better management features from the NOS for sometime, and metering is just one of the features which must be provided.⁶⁶

In response to this call, representatives of Digital Equipment Corporation, Microsoft Corporation, Novell Corporation, Highland Software, Inc., microcomputer managers and independent software managers met in December 1991 to discuss a preliminary specification for a proposed API. The draft specification, developed by Digital Equipment Corporation, defined which API calls must be made from an application program to a tracking database or metering utility program. The API would not limit the way an independent software vendor could implement its licenses or metering program because extensions to the metering programs would be allowed, although such extensions could lead to incompatibility among metering utilities.⁶⁷ One of the issues raised by such a common API, however, is the "dirty metering program." With a common API, the software developer can no longer control the metering program which will be used by the end user to manage the concurrent use licensing. As a result, even one defective, or "dirty," metering program could result in hundreds, or even thousands, of unauthorized

66. Keith Herron and Joanne Witt, *The MMA's White Paper on Network Software Licensing*, INFO WORLD, Oct. 14, 1991, at 46.

67. Stuart Johnston, *Group studies licensing API; DEC, Microsoft push for standard*, INFO WORLD, Dec. 9, 1991, at 1.

uses. Even worse, a system could be developed using the API to intentionally defeat the concurrent license scheme.

License manager software may also provide other useful information and protection to a network administrator, such as data concerning who has used the various resources on the LAN, how often such resources are used, what time of day they are used, and whether there are times when others are denied access to the resources, which may be helpful in planning future expansion of the network. Some metering systems also include virus protection and security features.⁶⁸ License manager software may also allow for managing different licensing schemes for different software programs. For example Highland Software Inc.'s network license manager software, Flexlm, can be used to meter concurrent use licensing, but it also allows a network administrator to place reservations on the system for a particular software program. This becomes the equivalent of a single CPU license without the problems of node-locking.⁶⁹

A license which does not clearly specify the scope of the license granted can have disastrous economic consequences for the software supplier. For example, a supplier who expects each copy of the software to be used on a single CPU will receive significantly less revenue if the license granted permits use of each copy of the software on a single CPU *at a time*. The pricing model would presumably require a higher per copy royalty for such concurrent use, and the supplier might be unwilling to knowingly permit such use without an appropriate license manager program.

Allocating Liability for Viruses on the LAN

Until recently LANs did not maintain any data of real value to a corporation. With companies downsizing from mainframe computers to LANs, this has changed. Companies are now storing and moving valuable customer files, financial information, payroll, personnel and order entry records over their LANs. The risks posed by computer viruses increase as records move from mainframe computers to LANs.⁷⁰ As one network manager noted, "In your traditional [information systems] center, you wouldn't allow a stranger to walk in, mount a tape and load programs onto a mainframe. Yet

68. Kimberly Maxwell, *Building Work Group Solutions: LAN Meeting Software*, PC, Sept. 11, 1990, at 295.

69. Mike Burgard, *A New Way to License Software*, UNIXWORLD, Dec. 1991, at 60, 62.

70. Computer viruses are programs that hide within a personal computer and replicate themselves, infecting floppy disks and programs transferred to other PCs.

every day, people carry floppy disks into work and load software onto LAN workstations."⁷¹

As the number of LANs grows, the number of viruses is also growing. Products less than a year old that search for "over 300 viruses" are almost laughable today. Security specialists cite documentation of more than 1,000 different strains of viruses. The National Computer Association estimates that by the end of 1994, there will be almost 40,000 different virus strains.⁷²

A study by the Data Processing Management Association found that 26% of the approximately 200 companies surveyed had experienced some kind of virus in January 1990 alone.⁷³ In December, 1991, Novell sent a letter to approximately 3800 customers, warning them that it had inadvertently allowed a destructive software virus known as "Stoned III," which can erase or garble everything stored on a hard disk, to invade copies of a Novell software disk shipped that month.⁷⁴

Sophisticated computer users are now using a multifaceted approach to computer viruses, which includes updating antivirus software regularly, backing up their records once a week and using virus scanners every time a PC is booted. They are also seeking to protect themselves contractually by including computer virus warranties and indemnities in their license agreements with software suppliers. Software suppliers should not lightly give such warranties, since introduction of a virus to a LAN can result in huge losses. According to John McAfee, President of McAfee & Associates, a Santa Clara antivirus firm, if Stoned III were to get into an organization and spread to 1500 machines, it would cost millions of dollars to clean up.⁷⁵ In a real life example of the potential losses which a virus can cause, the Computer Virus Industry Association did a detailed breakdown of costs associated with the virus that struck the federal Internet in November, 1988 and concluded that the virus resulted in \$98 million of damages.⁷⁶

In addition, it is extremely difficult to determine the origin of a

71. Salvatore Salamone, *How to Guard Nets Against Growing Virus Plague*, NETWORK WORLD, July 15, 1991, at 1, 49, 50.

72. Paul Melka, *Wishful Thinking Will Not Make Publicity-Seeking Viruses Go Away*, INFO WORLD, April 27, 1992, at 47.

73. *Have Computer Viruses Turned Into A Plague?*, BUSINESS WEEK, June 10, 1991, at 71.

74. John Markoff, *Novell Says Software Virus Invaded a Recent Product*, THE NEW YORK TIMES, Dec. 20, 1991, at D-1.

75. *Id.*

76. Salamone, *supra* note 71, at 50.

virus, since it can be introduced into a LAN by sharing floppy disks, using bootlegged software, or through dial-out or dial-in access to the LAN. As a result, if the software supplier gives such a warranty, it should require that its licensee be able to demonstrate that supplier's media was the source of the virus.

Warranting Software In a Networked Environment

Networks are becoming the lifeline of business as companies move their mission-critical applications to multiplatform networks. Network downtime, the time that the network is either down or degraded, can cause extreme monetary loss, particularly when it affects mission-critical data. In recent studies, major corporations have reported capital losses of astounding magnitude when they have had problems with their networks. One study indicated the average lost productivity resulting from network problems to be in excess of three million dollars per year.⁷⁷ Errors, or "bugs," in computer programs which cause minor problems when used on a standalone PC can cause major disruptions in a LAN by destroying shared data files, crashing the network, or producing wrong results which are quickly replicated and relied upon throughout the organization. The frequency of bugs also increases due to the increased complexity of network aware software and the inability of software developers to test their programs on the multitude of possible combinations of hardware and operating system environments which may be found in a LAN. Isolation of the cause of faults on a LAN also becomes difficult as the LAN grows in size and complexity.

The typical warranty included in a shrinkwrap license for prepackaged software does not adequately address the increasingly complicated environment in which the software will be used. It is difficult to imagine that a court will uphold a warranty offered by many suppliers of shrinkwrapped applications, which is limited to defects in the media, when the user is paying thousands of dollars to use the program on multiple nodes. Yet, the software supplier should be hesitant to provide the other typical warranty for shrinkwrapped applications - that the software will perform substantially in accordance with the end user documentation - without clearly specifying the hardware and software environment in which the application will be run. Because a supplier may be forced to spend hours trying to isolate the bug in its software only to discover that the fault has occurred in another component of the network, the

77. Steven M. Dauber, *Finding Fault*, BYTE, March 1991, at 207.

prudent software supplier may wish to include a provision in its warranty that allows it to be compensated at its then current consulting rates for time expended to identify a bug if it is subsequently determined that the reported problem was not caused by the supplier's program. Because destruction of mission-critical data may result in damage to the licensee far in excess of the license fee for its program, the software supplier should also include a disclaimer of any liability for such destruction or loss.

CONCLUSION

This article has attempted to provide a basic understanding of LANs in order to assist in the development of "network aware" licenses which recognize and proactively deal with the movement of software from standalone computers to multiple computers in a networked environment.

APPENDIX

*Licensing Methods*1. *Per CPU Licensing.*

a. *Single CPU at a time (Use in a LAN is not permitted):* Licensee may use the Software on a single central processing unit at a time. Licensee agrees to treat this Software just like a book, except that Licensee may not rent, lease, or license the Software to others. This means that, like a book, any number of people may use the Software sequentially, and it may be moved freely from one computer to another, so long as there is no possibility of it being used at two different locations at a time. Thus, for example, Licensee cannot share this Software on a local area network. If Licensee wishes to use the Software on more than one computer at a time, Licensee must license such rights from Licensor. Licensee may not electronically transfer the Software from one computer to another over a network.

b. *Single Designated CPU (Use in a LAN is not permitted):* Licensee may use the Software on a single designated central processing unit [at a designated site] [and in connection with a designated segment of Licensee's business]. "Designated CPU" means the complete equipment listed in Exhibit A hereto or any substituted or backup equipment designated in writing by Licensee and approved by Licensor. Licensee may move the Software to another site which physically replaces the original site upon prior written notice to Licensor [and approval thereof by Licensor]. Licensee agrees to refrain from using the Software on a network or for other sites or premises or on a timeshare or other service basis.

c. *Single CPU at a time (Use in a LAN is permitted):* Licensee may use the Software on a single central processing unit at a time, except that the Software may be executed from a common disk shared by multiple CPUs provided that one authorized copy of the Software has been licensed from Licensor for each CPU executing the Software. Licensee agrees to treat this Software just like a book, except that Licensee may not rent, lease, or license the Software to others. If the single computer on which Licensee uses the Software is a multiuser system, the license limits use to a single user at a time on that single system. This license allows you to copy the Software over a network for use on a single CPU, provided that the network is only accessible to your organization.

d. *Single Designated CPU (Use in a LAN is permitted):* Licensee may use the Software on any single personal computer sys-

tem (whether a standard computer or a workstation component of a multi-user network) (the "Designated CPU") and copy the Software solely for the purpose of installing it on the Designated CPU (hard disk or other device), loading the Software into RAM, or creating a backup or archival copy. An alternate CPU may be submitted for the Designated CPU in the event that the Designated CPU becomes inoperable or may replace the Designated CPU, provided that use of the Software on the Designated CPU is terminated and Licensor is immediately notified in writing of the identity and of the successor CPU. Licensee may not copy the related documentation or supporting materials accompanying the Software.

e. *Description of Node-Locked Mechanism*: Licensor shall provide Licensee with a password corresponding to the equipment Host ID number ("Authorized Equipment") listed on Licensee's purchase order or Licensor's sales order or invoice. This password enables the "Save" feature of the Software when the Software is used on the Authorized Equipment. Otherwise, the "Save" feature is disabled and what shows on the screen may not be stored. If Licensee desires to enable the "Save" feature on other pieces of equipment in addition to the Authorized Equipment, then Licensee may do so by notifying Licensor of the Host ID Number of such equipment and paying to Licensor the amount listed on the then-current price list. Licensor will then provide Licensee with a password which will enable the "Save" feature on such equipment and the list of Authorized Equipment will be accordingly expanded.

2. *Per User Licensing.*

a. *Per User/Single Computer (Use in a LAN is not permitted)*: Licensee may use the Software on a single computer at a time provided that access to the Software is limited to a single user. Licensee cannot share the Software on a local area network; if more than one user wishes to use the Software or if Licensee wishes to use the Software on a network, Licensee must license such rights from Licensor.

b. *Per User (Use in a LAN is permitted)*: Licensor grants Licensee the right to use one copy of the Software on a single terminal connected to a single computer (i.e. with a single CPU), or on a Licensed Computer Network. A Computer Network is any combination of two or more terminals that are electronically linked and capable of sharing the use of a single software program. A Licensed Computer Network is a computer network for which Licensee has purchased and dedicated at least one (1) Software manual (which

can include an instruction manual or manuals for the single-user of the Software) for each user of the Software on the network. Each user of the Software must have exclusive access to a Software manual during his use.

c. *Per User (Use in a LAN is permitted/Home Use permitted):* Licensee may use the Software on a single networked group of computers which share a common disk drive on which the Software is stored, provided that access to the Software is limited to a single user. Provided that each user uses the Software more than 80% of the time on a system located within Licensee's faculty, then that user may also use the Software on a portable and/or home computer.

3. *Server-Based Licensing.* If this Software is a network version, Licensee may install one copy of the Software on a Network Server for use on a single local area network and may only copy such Software for backup or archival purposes. For purposes of this Agreement, a workstation may include a server. A "Network Server" is a computer managing access to shared resources including files, disks, printers, or other peripherals, used by other workstations connected to the network.

4. *Site Licensing.* Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee the following license and rights:

a. A perpetual, nonexclusive license to use the Software for its own administrative and accounting purposes in the United States on any CPU located at a Site for which the License Fees for the Software have been paid. An alternate Site may be substituted for a Site provided that use of the Software at the original Site is terminated and Licensor is immediately notified in writing of the location of the successor Site. This license [does not] include[s] the right to download portions of the Software for use on computers located at Remote Access Locations and to provide remote access to the Licensed Software from terminals located at such Remote Access Software [solely for Licensee's internal business purposes]. In the event of an equipment malfunction causing the Software to become inoperable at a Site, Licensee may use the Software at back-up Site on a temporary basis until the malfunction is corrected.

b. Licensee understands and agrees that use of the Software for the purposes of providing data processing services to third parties, such as commercial use in a service bureau or timesharing arrangement, or its transfer to any person or entity outside the country, or its use at any Site other than those Sites for which the

License Fees for the Software have been paid or their successors (other than its use at Remote Access Locations pursuant to subparagraph a. above), is strictly prohibited.

5. *Concurrent Use Licensing.*

a. *Concurrent Use, No Metering Utility Required:* Licensee may use the Software on a series of single computers or a single networked group of computers, not to exceed the License Limit purchased. Licensee may physically transfer the Software from one computer to another computer owned or leased by Licensee provided that the maximum number of copies of the software that are used at any one time does not exceed the License Limit.

b. *Concurrent Use, Metering Utility Required:* Licensee may use the Software on a Licensed Computer Network provided that Licensee has purchased the Server edition of the Software and installed the license manager software program included with the Server edition. A "Computer Network" is any combination of two or more terminals that are electronically linked and capable of sharing a single software program. A "Licensed Computer Network" is a Computer Network on which Licensee has installed the license manager software program. The license manager software program restricts the concurrent use of the Software to the number of licenses which Licensee has purchased. For example, if there are three (3) computers which are concurrently using the Software on the server, then Licensee must purchase a minimum of three concurrent use licenses.

c. *Multi-Pack License Grant:* A registration number which enables the Software is included, which corresponds to the number ("Number") of concurrent users listed on Licensee's purchase order. If a Number greater than one applies to the Software, and Licensee desires to increase the size of the Number, then Licensee may do so by notifying its place of purchase of the desired Number increase, and paying the applicable purchase price to Licensee's place of purchase. The place of purchase will provide Licensee with a registration number which will effect the Number.

d. *Multi-Pack License Grant with License Manager Program:* Each single user software package permits one user to access the Software at a time, and each five-pack authorizes five additional simultaneous users. Licensee can increase the number of authorized concurrent users by purchasing additional single-user or five-pack packages. The five-pack comes with an extra disk containing a license manager software program. If Licensee wishes to increase its

user count, Licensee may run the license manager software program and type in the five-count serial number allotted with the five-pack. The five-pack can be installed only in a network shared hard disk, and it operates only in conjunction with an installed single user package. Licensee cannot operate the five-pack by itself.

COMPUTER VIRUS PROVISIONS

1. *Definition of Computer Virus:* A "Computer Virus" is an undocumented and unauthorized program designed to cause loss of, or damage to, data files; or gain access to, and/or interfere with, the operation of, other programs or computer resources, or any other results not intended by the user of the computer system on which the virus program resides.

2. *Computer Virus Warranty:* Licensor represents and warrants that there are no Computer Viruses in the software.

3. *Computer Virus Screening Provision:* Licensor shall use due diligence in screening all Software to be delivered to Licensee in order to minimize the possibility of the introduction of a Computer Virus. If Licensor fails to perform such screening with the result that an identified and acknowledged Computer Virus is introduced into the Licensee's systems, Licensor shall be responsible for any loss, damage or liability caused by such Computer Virus. If Licensor performs such screening, but a new or unidentified Computer Virus is nevertheless introduced into Licensee's systems through Licensor's Software, Licensor shall only be liable for the value of the Software that Licensor supplied.

4. *Computer Virus Screening Provision and Disclaimer of Computer Virus Warranty:* The parties acknowledge the need to cooperate to reduce the risk that a Computer Virus will be introduced into Licensee's computing environment on media supplied by Licensor. Licensor agrees to use a commercially-available anti-virus screening program to screen all media containing the Software before such media are delivered to Licensee. Licensee acknowledges that Licensor does not represent or warrant that the media delivered by Licensor will be Computer Virus-free. Licensee agrees to employ a commercially available anti-virus screening program to screen all media delivered by Licensor to Licensee. Licensor's sole liability, if Licensee's screening procedure detects a Computer Virus or such media or if Licensee is otherwise able to demonstrate that media supplied by Licensor is the source of a Computer Virus introduced into Licensee's computing environment, will be to deliver

new copies of the Software on media free of the identified Computer Virus, at no charge to Licensee.

Network Aware Warranty

Express Warranty: Licensor warrants that the Software will perform substantially in accordance with the published documentation for such Software (the "Documentation"), only when operated on or in conjunction with the hardware and software with which the Software was designed to be used as described in the Documentation, during the ninety (90) day period following delivery of the Software Licensee (the "Warranty Period").

Exclusive Remedies: Licensee's exclusive remedy, and Licensor's entire liability in contract, tort or otherwise, shall be to use its best efforts to provide a correction or workaround for any substantial nonconformity of the Software with the Documentation ("Error") which is (a) reported to Licensor by Licensee during the Warranty Period and (b) reproducible by Licensor in the execution environment. If, however, after repeated efforts, Licensor is unable to provide a correction or workaround for any reported Error, then Licensee's exclusive remedy and Licensor's entire liability in contract, tort, or otherwise shall be for licensor to refund the amounts paid by Licensee for the Software upon Licensee's return of the original and all copies of the Software in its possession, together with its certification that it has ceased all use and distribution of the Software.

Exceptions from Warranty: The warranties set forth above shall not apply to any defects or problems caused in whole or in part by (i) any defect in any portion of any hardware or equipment, (ii) the failure of any portion of any hardware or software to function in accordance with applicable manufacturer's specifications, (iii) any modification or enhancement to the Software by Licensee or any third person or entity other than Licensor; (iv) the failure of Licensee or any third person or entity to follow the most current instructions promulgated by Licensor from time to time with respect to the Software; or (v) the negligence of Licensee or any other third party or entity. Licensor shall not be responsible in any manner for errors or failures in proprietary systems, hardware or software other than those of Licensor. It is Licensee's responsibility to maintain backup data to be able to regenerate or duplicate data in the event of loss. In the event that Licensor determines that any warranty claim reported by Licensee falls within any of the forego-

ing exceptions, Licensee shall pay Licensor for its services at Licensor's hourly rates than in effect.

Disclaimer of Express or Implied Warranties: EXCEPT FOR THE EXPRESS WARRANTIES STATED IN THIS AGREEMENT, LICENSOR MAKES NO ADDITIONAL WARRANTIES EXPRESS, IMPLIED OR STATUTORY, AS TO ANY MATTER WHATSOEVER. IN PARTICULAR, ANY AND ALL WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT OF THIRD PARTY RIGHTS ARE EXPRESSLY EXCLUDED. LICENSOR DOES NOT WARRANT THAT THE FUNCTIONS CONTAINED IN THE SOFTWARE WILL MEET LICENSEE'S REQUIREMENTS OR THAT THE OPERATION OF THE SOFTWARE WILL BE UNINTERRUPTED OR ERROR FREE.

THE PATENTABILITY OF ALGORITHMS: AN UPDATE ON THE STATUS OF THE CURRENT DOCTRINE

Alan D. Minsk*

INTRODUCTION

In a previous article I discussed the development of the legal doctrine regarding the patentability of algorithms.¹ I also attempted to indicate some of the problems with the current formulation of the doctrine, as well as issues which might benefit from further judicial clarification. This article is intended to discuss developments that have occurred since the writing of that article which have an impact on the status of the doctrine.

In general terms, these developments can be divided into three categories: 1) a decision of the Federal Circuit discussing whether particular patent claims were directed to statutory subject matter as defined by 35 U.S.C. § 101 and addressing an issue left open by the previous decisions; 2) a decision of the Board of Patent Appeals and Interferences directed to further defining, or clarifying previous definitions of the term "mathematical algorithm"; and 3) decisions addressing the apparent conflict between the Federal Circuit and the U.S. Patent and Trademark Office as to the proper interpretation and application of 35 U.S.C. § 112, Paragraph 6.² This article discusses the recent cases which are relevant to each of these developments and concludes with some comments on the doctrine as it now stands.

Copyright © 1993 by Alan D. Minsk.

* Associate, Limbach & Limbach, San Francisco, CA.; J.D. 1991, Harvard Law School; M.A. 1981, University of California at Berkeley; A.B. 1979, University of California at Berkeley. Mr. Minsk is also registered to practice before the U.S. Patent and Trademark Office.

1. Alan D. Minsk, *The Patentability of Algorithms: A Review and Critical Analysis of the Current Doctrine*, 8 SANTA CLARA COMPUTER & HIGH TECH. L.J. 251.

2. The text of the cited paragraph is:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. 35 U.S.C. § 112, ¶ 6.

1. The Federal Circuit Decision

*Arrhythmia Research Technology, Inc. v. Corazonix Corp.*³ is the most recent Federal Circuit decision involving the patentability of algorithms. *Arrhythmia* involved claims directed to an apparatus and method for analyzing electrocardiograph signals to determine certain characteristics of the heart function as evidenced by those signals.⁴ The purpose of the claimed invention was to determine which heart attack victims were at a high risk for developing an acute type of heart arrhythmia known as ventricular tachycardia.⁵ This was done in order that those patients at risk could be carefully monitored and given the appropriate treatment.⁶

A patent containing the apparatus and method claims had issued and was the subject of an infringement suit in which its validity was challenged.⁷ The lower court granted a motion for summary judgment declaring the patent invalid for failure to claim statutory subject matter because the claims were directed to a mathematical algorithm.⁸ The patentee appealed to the Federal Circuit, which reversed the judgment of the lower court.⁹

The claimed invention involved obtaining certain of the heart attack patient's electrocardiograph signals, converting them from analog to digital values, forming a digital representation of the relevant portion of the signals by averaging a large number of the waveforms, processing the composite waveform by a digital high pass filter in reverse time order, determining the average magnitude of the processed waveform, and comparing the magnitude of the processed waveform to a predetermined value.¹⁰ The result of the comparison step was an indication of whether the patient was at higher risk for the onset of ventricular tachycardia.¹¹

Certain steps of the invention were described in the specification section of the patent application as being conducted with the aid of a digital computer.¹² The mathematical formulae used to program the computer were also indicated.¹³ The specification

3. 958 F.2d 1053 (Fed. Cir. 1992).

4. *Id.* at 1054.

5. *Id.*

6. *Id.*

7. *Id.* at 1058.

8. *Arrhythmia*, 958 F.2d at 1054.

9. *Id.*

10. *Id.* at 1055.

11. *Id.*

12. *Id.*

13. *Arrhythmia*, 958 F.2d at 1055.

stated that dedicated, specific purpose equipment or hard wired logic circuitry could also be used.¹⁴ The Patent and Trademark Office (PTO) had granted the patent without raising the issue of whether its claims were directed to statutory subject matter.¹⁵

The Court began its opinion by recognizing the presumption of validity which attaches to a duly issued United States patent.¹⁶ The Court then recited the text of 35 U.S.C. § 101.¹⁷ The Court followed by reviewing the development and current status of the doctrine regarding the patentability of algorithms, citing the relevant Supreme Court, Federal Circuit, and Court of Customs and Patent Appeals decisions.¹⁸ The Court summarized the doctrine by stating: The law crystallized about the principle that claims directed solely to an abstract mathematical formula or equation, including the mathematical expression of scientific truth or a law of nature, whether directly or indirectly stated, are nonstatutory under section 101; whereas claims to a specific process or apparatus that is implemented in accordance with a mathematical algorithm will generally satisfy section 101.¹⁹

The Court then referred to the two-stage analysis which had been adopted for use when determining whether patent claims involving algorithms were directed to statutory subject matter, (i.e., the *Freeman-Walter-Abele* test).²⁰ The Court then applied the two stage analysis separately to the group of process claims and to the group of apparatus claims.²¹

Beginning with the process claims, the Court stated, "[W]e accept for the purposes of this analysis that a mathematical algorithm is included in the subject matter of the process claims in that some

14. *Id.*

15. *Id.*

16. "Thus we give plenary review to the question [of whether the claims are directed to statutory subject matter], with appropriate recognition of the burdens on the challenger of a duly issued United States patent. See 35 U.S.C. § 282." *Arrhythmia*, 958 F.2d at 1056.

17. *Id.*

18. The interested reader will find a discussion of these cases and a critical analysis of their content in my previous paper.

19. *Arrhythmia*, 958 F.2d at 1058.

20. The *Freeman-Walter-Abele* test is a two-part test designed to assist courts with their analysis of patent claims reciting algorithms. It can be briefly stated as: 1) Does the claim directly or indirectly recite an "algorithm" in the *Benson* sense of that term? Here the reference is to the definition of an algorithm cited in *Gottschalk v. Benson*, 409 U.S. 63 (1972), (i.e., "a procedure for solving a given type of mathematical problem"); and 2) Is the algorithm applied in any manner to physical elements or process steps, provided that its application is circumscribed by more than a field of use limitation or non-essential post-solution activity?

21. *Arrhythmia*, 958 F.2d at 1058-60.

claimed steps are described in the specification by mathematical formulae."²² With the first stage of the analysis completed, the Court proceeded to the second stage. The Court noted that the process claims included a limitation to a particular field of use, i.e., analysis of electrocardiograph signals for a specific purpose.²³ The Court indicated that this limitation was of some importance as it "is not ignored in determining whether the subject matter as a whole is statutory, for all of the claim steps are in implementation of this method."²⁴

It is worth noting that the claim language cited by the Court is found in the preamble to the claims.²⁵ This raises the separate issue of whether such a limitation is of patentable weight. The use of a field of use limitation in the preamble to a claim was addressed in the context of algorithms in an earlier decision of the Supreme Court, where it was found to be insufficient, by itself, to confer patentability.²⁶

In *Arrhythmia*, the Court's later comments suggest that what was of the most significance to the patentability determination in the case was that something physical was being operated upon.²⁷ In addressing the issue of the abstractness or intangibility of the claimed process, the Court stated, "[t]he resultant output [of the process steps] is not an abstract number, but is a signal related to the patient's heart activity."²⁸ The Court goes on to say "[t]hese claimed steps of 'converting', 'applying', 'determining', and 'comparing' are physical process steps that transform one physical, electrical signal into another."²⁹

The Court concluded its analysis of the process claims by stating, "[t]he *Freeman-Walter-Abele* standard is met, for the steps of Simson's claimed method comprise an otherwise statutory process whose mathematical procedures are applied to physical process steps. The method claims do not wholly preempt these procedures, but limit their application to the defined process steps. The process

22. *Id.* at 1058.

23. "Simson's process is claimed as a 'method for analyzing electrocardiograph signals to determine the presence or absence of a predetermined level of high-frequency energy in the late QRS signal'." *Arrhythmia* 958 F.2d at 1059.

24. *Id.*

25. *Id.* at 1055.

26. *See Parker v. Flook*, 437 U.S. 584 (1978). This decision implies that limitation to a specific field of use, without more, is insufficient, if the claims recite a mathematical algorithm.

27. *Arrhythmia*, 958 F.2d at 1059-60.

28. *Id.* at 1059.

29. *Id.*

claims comprise statutory subject matter.”³⁰

The Court then discussed the apparatus claims, noting that “[t]he Simson apparatus for analyzing electrocardiograph signals is claimed in the style of 35 U.S.C. § 112, paragraph 6”.³¹ This refers to the practice of claiming elements of a combination by use of means-plus-function language. The Court went on to discuss the claim language with reference to the specific means for implementing the claimed structure which was referred to in the specification. The Court concluded that “[t]he Simson apparatus claims thus define ‘a combination of interrelated means’ for performing specified functions.”³²

The Court again addressed the intangibility issue by stating “[t]he claimed invention . . . converts one physical thing into another physical thing just as any electrical circuitry would do”.³³ The Court then commented on the Appellant’s assertion that “the final output of the claimed apparatus (and process) is simply a number, and that *Benson* and *Flook* support the position that when the end product is a number, the claim is nonstatutory and can not be saved by claim limitations of the use to which this number is put.”³⁴ The Court addressed this argument by emphasizing that the result of the claimed invention was not an abstract quantity, but represented a tangible, concrete measure.³⁵ The Court concluded its analysis of the apparatus claims by stating “[t]he Simson apparatus claims satisfy the criteria for statutory subject matter. They are directed to a specific apparatus of practical utility and specified application, and meet the requirements of 35 U.S.C. § 101.”³⁶

In keeping with the earlier decisions the *Arrhythmia* decision supports the patentability of applications of algorithms. It also emphasizes the importance of tying the operation of the algorithm to something physical, in this case the manipulation of electrical signals which represent a physical entity. With regards to the language of the method and apparatus claims themselves, it is worth

30. *Id.* at 1059-60.

31. *Id.* at 1060. See note 2 of this article for the text of the cited paragraph.

32. *Id.*, citing *In re Iwahashi*, 888 F.2d 1370, 1375 (Fed. Cir. 1989).

33. *Arrhythmia*, 958 F.2d at 1060, citing *In re Sherwood*, 613 F.2d 809, 819 (CCPA 1980), *cert. denied*, 450 U.S. 994 (1981). This citation by the Court is reminiscent of the language from the *Cochrane v. Deener* case cited by the Supreme Court in *Benson*, although that language referred to a process claim. See 409 U.S. 63, 70.

34. *Arrhythmia*, 958 F.2d at 1060.

35. “[T]he number obtained is not a mathematical abstraction; it is a measure in microvolts of a specified heart activity, an indicator of the risk of ventricular tachycardia.” *Id.*

36. *Arrhythmia*, 958 F.2d at 1060.

noting that the broad method claim cited in the decision implicitly claims an element of physical structure, i.e., ("high pass filter means"), while the apparatus claim cited in the decision is written in means plus function language, except for one element, again a "high pass filter means".³⁷

The use of language reciting an element of physical structure limits the scope of the claims and avoids the intangibility and pre-emption problems which plagued algorithm claims in other cases. The restriction of the operation of the algorithm to electrocardiograph signals makes the claimed invention concrete rather than abstract. The combination of these factors enable the claim language to overcome most of the prior objections to patenting algorithms. Thus *Arrhythmia* indicates how method claims drawn to an algorithm can be patented. If the claims are tied to something physical, as in transforming something physical from one form to another, the § 101 hurdle can be overcome. With regards to the apparatus claims, the decision supports the *Iwahashi* approach and further indicates that § 101 can be satisfied by claiming physical elements which operate or are transformed in a way constrained by the algorithm.

A final note on the decision is that it includes a lengthy concurring opinion from Justice Rader.³⁸ The concurrence, presents a thorough commentary on the pitfalls of the doctrine, with particular emphasis on Justice Rader's opinion that the Supreme Court opinions after *Benson* had strictly limited that decision, and in doing so, had "refocused the patentability inquiry on the terms of the Patent Act rather than on non-statutory, vague classifications".³⁹ Justice Rader also mentions specific problems with the two-stage *Freeman-Walter-Abele* test for statutory subject matter.⁴⁰

2. The Board of Patent Appeals and Interferences Decision Discussing the Definition of the Term "Mathematical Algorithm"

*In re Pardo*⁴¹ had limited the holding in *Benson* to "mathematical algorithms". This meant that in order to apply *Benson* and the resulting *Freeman-Walter-Abele* test, it was necessary to determine what constituted such an entity. This is actually a complicated

37. *Id.* at 1055.

38. *Id.* at 1061-66.

39. *Id.* at 1066.

40. The interested reader is encouraged to examine the concurrence, and/or my previous article which points out similar problems with the doctrine.

41. 684 F.2d 912 (CCPA 1982).

question, because it is difficult to reach agreement on what is meant by the term. Earlier courts had addressed this question, although their solutions seem overinclusive.⁴²

The U.S. Patent and Trademark Office Board of Patent Appeals and Interferences (Board) stepped into the fray with its decision in *Ex Parte Logan*.⁴³ This case concerned a patent application which contained claims drawn to "an apparatus for detecting inspiration of a patient in response to a time varying signal representative of the patient's respiration."⁴⁴ In discussing the Examiner's rejection of the claims at issue, the Board reviewed the standard two-step test for non-statutory subject matter.⁴⁵ Since application of the test necessitates the determination of whether the claims recite a mathematical algorithm, the Board included comments on the matter.

The Board first cited the *Benson* definition of the term, and then expanded on it through examples. "Mathematical algorithms include mathematical equations and formulas for calculating a numerical output value from a number of numerical input values, whether directly or indirectly claimed."⁴⁶ The Board then mentioned that mathematical algorithms were not limited to those categories it had previously listed, but included "methods of calculation".⁴⁷ In discussing this category of non-statutory algorithms, the Board stated "the *essence* of a method of calculation in the § 101 sense, whether it is in the form of mathematical formula or equation or some other form, is the *computation of one or more numbers from a different set of numbers by performing a series of mathematical computations*."⁴⁸

The Board then presented a summary of its interpretation of the appropriate definition of a mathematical algorithm. "[W]e believe a claim should be considered as reciting a mathematical algorithm, only if it *essentially* recites, directly or indirectly, a method of computing one or more numbers from a different set of numbers by performing a series of mathematical computations."⁴⁹

42. See *In re Walter*, 618 F.2d 758, 764 n. 4 (CCPA 1980) (methods of calculation, mathematical formulas, and mathematical procedures). See also *In re Pardo*, 684 F.2d at 916 (mathematical formula, calculation, or algorithm).

43. 20 U.S.P.Q.2d 1465 (Bd. Pat. App. & Int. 1991).

44. *Id.* at 1466, citing claim 1 of the application.

45. *Id.* at 1467.

46. *Logan*, 20 U.S.P.Q.2d at 1467.

47. *Id.*

48. *Id.* at 1467-68 (emphasis in original).

49. *Id.* at 1468 (emphasis in original). The Board followed this statement with the comment, "[c]onsequently, a claim which essentially recites another type of method does not

One way of interpreting the Board's definition of a mathematical algorithm is that it focuses on whether the claims at issue are essentially attempting to protect the mathematical operations involved in "computing one or more numbers from a different set of numbers." This can be viewed as providing a better definition of what the Court in *Benson* was referring to in its definition of an algorithm. The "procedure for solving a given type of mathematical problem" referred to in *Benson* may simply mean those computations or operations used to produce a final output (the solution of the problem) from a set of inputs.

One commentator has interpreted the Board's decision as "severely limit[ing] the definition of unpatentable subject matter" and that the Board "narrow[ed] the scope of the definition of a mathematical algorithm".⁵⁰ Whether this is true remains to be seen. It is also not clear what influence, if any, the Board's decision will have on the courts. However, this decision may become significant if it affects how examiners in the Patent and Trademark Office view claims which recite mathematical computations.

3. The Conflict Between the Federal Circuit and the
Patent and Trademark Office Over the Proper
Interpretation and Application of 35 U.S.C.
§ 112, ¶ 6

In my previous article, I referred to the possibility of a difference in opinion between the Federal Circuit and the Patent and Trademark Office as to the proper interpretation and application of 35 U.S.C. § 112, ¶6.⁵¹ As subsequent decisions of the Federal Circuit and Board have indicated, this is indeed a fertile area for disagreement, or at least heated discussion.

The current round of the argument between the Federal Circuit and the PTO over the appropriate interpretation of 35 U.S.C. § 112, ¶6, at least in the context of a patent examiner's review of the claims in a patent application, was initiated by the Federal Circuit's decision in *In re Iwahashi*.⁵² Although the Court's comments in that case regarding 35 U.S.C. § 112, ¶6 were dicta, it is apparent that the Court favors a literal interpretation of that portion of the statute, both in the context of ex parte proceedings before the PTO

recite a mathematical algorithm, even though it incidentally requires, either directly or indirectly, the performance of some mathematical computations." *Id.*

50. Irah Donner, *Patenting Mathematical Algorithms That 'Embrace' Mother Nature*, 9 THE COMPUTER LAWYER 10 (May 1992).

51. See 8 SANTA CLARA COMPUTER & HIGH TECH. L.J. 251 at 279-80.

52. 888 F.2d 1370 (Fed. Cir. 1989).

and inter partes proceedings before a court.⁵³

The Court took the opportunity to formalize its dicta in *Iwahashi* in the case of *In re Bond*.⁵⁴ *Bond* concerned a patent application directed to a specific remote control feature of a telephone answering machine, the remote turn-on feature.⁵⁵ The inventor had claimed a combination of prior art technology (which enabled an owner of the machine to remotely set it to answer incoming calls) with a delay means which would prevent the machine from answering the owner's initial call for a predetermined period after being set to answer incoming calls.⁵⁶ This was designed to prevent the owner from incurring any toll charges while setting the machine.⁵⁷ The claims of the application were rejected by an examiner under 35 U.S.C. § 102 and § 103 over two prior art patents.⁵⁸

In comparing the prior art to the claims at issue, the Court stated:

The disclosed and prior art structures are not identical, but the claim may nonetheless be anticipated. While a "means-plus-function limitation" may appear to include all means capable of achieving the desired function, the statute requires that it be "construed to cover the corresponding structure, material, or acts described in the specification and *equivalents thereof*".⁵⁹

Thus, the Court left no doubt as to how it viewed the PTO's obligations where section 112 ¶6 was concerned. During the examination of patent applications, PTO examiners were to limit the scope of claims phrased in means-plus-function language based on the con-

53. "In the Solicitor's brief the summary of argument states that the claim [at issue in the case] 'encompasses any and every means for performing the functions recited therein'. We point out that . . . [t]he claim is . . . subject to the limitation stated in 35 U.S.C. § 112 ¶6 . . . This provision precludes the Solicitor's interpretation of the claim." 888 F.2d at 1375. In an accompanying footnote the Court further stated, "Section 112 ¶6 cannot be ignored when a claim is before the PTO any more than when it is before the courts in an issued patent." *Id.* at n. 1. The PTO responded to the Court's dicta in *Notice Interpreting In re Iwahashi*, 1112 OG 18 (1990). The PTO expressed concern that a claim expressed entirely in means-plus-function language would, under the Court's dicta, be distinguishable from a method claim if the content of the specification (as suggested by application of 35 U.S.C. § 112, ¶6), rather than the literal claim language was determinative when undertaking a statutory subject matter analysis. This, the PTO stated, "would be directly contrary to precedent." 1112 OG at 19.

54. 910 F.2d 831 (Fed. Cir. 1990), reh. denied Nov. 1, 1990.

55. *Id.* at 832.

56. *Id.*

57. *Id.*

58. *Id.*

59. *Bond*, 910 F.2d at 833 (emphasis in original), citing 35 U.S.C. § 112, ¶6, *Iwahashi*, and *Johnston v. Ivac Corp.*, 885 F.2d 1574 (Fed. Cir. 1989)(section 112 ¶6 operates to cut back on the types of means which could literally satisfy the claim language).

tent of the specification. This precludes an expansive interpretation of such claim language and can act to prevent the rejection of such claims based on prior art.

The PTO responded to *Bond* in *Notice, Applicability of the Last Paragraph of 35 U.S.C. § 112 to Patentability Determinations Before the Patent and Trademark Office*.⁶⁰ In the *Notice*, the PTO reviewed the applicability of § 112, ¶6 to ex parte patentability determinations based on the statutory language, legislative history, CCPA decisions, long-standing PTO interpretations, legislative reenactment, and Federal Circuit cases.⁶¹ Having done so, the PTO concluded that "the clause does not apply."⁶²

Without going into detail, it appears that the PTO's argument is based on two primary considerations, and several secondary ones.⁶³ The primary considerations are the binding precedent of *In re Lundberg*⁶⁴, and the PTO's assertion that the language used in § 112, ¶6 has been interpreted by courts, including the U.S. Supreme Court, to refer to the context of infringement actions and not to patentability determinations by the PTO.⁶⁵ The secondary considerations include Congressional reenactment of § 112, ¶6 which "implicitly adopted and re-adopted the PTO/CCPA interpretation", the assertion that § 112, ¶6 acts like the reverse doctrine of equivalents, the presumption of validity conferred on an issued patent, and policy considerations related to the PTO's workload and the clarity of claims incorporating means-plus-function language if § 112, ¶6 were read literally.⁶⁶

While some of the PTO's arguments are persuasive, they do not directly address the issue of whether *Bond* is now binding precedent, or perhaps more accurately, why it is not. *Bond* arose in the

60. 1334 OG 631, [hereinafter the *Notice*] (Jan. 1992). The content of the *Notice* is reprinted, largely verbatim, in Ex parte Isaksen, 23 USPQ2d 1001 (Bd. Pat. App. & Int. 1991).

61. 1334 OG at 631.

62. *Id.* at 631.

63. A thorough review and critical analysis of the *Notice* is presented in Adamo, *Do the Means Justify the End - A Matter of Bond, Bowles, The Office and 35 U.S.C. § 112, Paragraph 6*, 74 JPTOS No. 8, pp. 566-596 (August 1992). The same author provides an updated interpretation and slightly different conclusion as to the status of the conflict between the Federal Circuit and the PTO in *The Double Standard - In re Bond, The Office, 35 U.S.C. § 112, ¶6 and Atlantic Thermoplastics Co.*, 2 FEDERAL CIRCUIT BAR JOURNAL No. 2, pp. 137-179 (Summer 1992).

64. 244 F.2d 543 (CCPA 1957).

65. The PTO maintains that courts have used the language 'construed to cover' from § 112, ¶6 "only to refer to post-issuance court matters and not to PTO patentability determinations". 1134 OG at 633.

66. 1134 OG at 634-35.

context of claim rejections during PTO review of a patent application based on prior art cited by the examiner.⁶⁷ Thus, *Bond* appears to be directly contrary to the "binding precedent" cited by the PTO. Even if in a later case the Federal Circuit were to explicitly overturn *Lundberg*, the PTO's comments suggest that it would still be reluctant to adopt the literal interpretation of § 112, ¶6 in patentability determinations.

To make its position clear, the PTO followed *Bond* with its own decision on the issue, *Ex parte Bowles*.⁶⁸ *Bowles* involved an appeal from a final rejection by the examiner in a reexamination proceeding of a patent containing claims drawn to a fluid amplifier system.⁶⁹ The Board first stated its opinion of what the proper role of the specification was in the context of claim interpretation, citing the Federal Circuit.⁷⁰ The Board then concluded, "while we have made every effort to liberally interpret the claims in light of the specification, it would be error on our part to infer or read into these claims any limitations from the specification."⁷¹

The Board then noted that the Appellants had argued that "'means plus function' limitations in the claims on appeal must as a matter of law be interpreted [in accordance with a literal reading of 35 U.S.C. § 112, ¶6]."⁷² The Board cited *Lundberg* and noted that "[a]t this time we are unable to reconcile the holding of *Lundberg* with that of *Bond*. We merely point out that *Lundberg* is regarded as binding precedent by our reviewing court. If a conflict exists between *Lundberg* and the panel decision in *Bond*, the earlier *Lundberg* decision is binding."⁷³

A still further twist to the controversy has been noted by a commentator.⁷⁴ The central issue seems to be whether claim language is to be interpreted in a different manner depending upon the context in which that interpretation is being made, (i.e., a patentability determination by the PTO versus a validity decision or in-

67. *Bond*, 910 F.2d at 832.

68. 23 USPQ2d 1015 (Bd. Pat. App. & Int. 1991).

69. *Id.* at 1016.

70. "It is entirely proper to use the specification to interpret what the Patentee mean by a word or phrase in the claim. But this is not to be confused with adding an extraneous limitation appearing in the specification, which is improper. Where a specification does not require a limitation, that limitation should not be read from the specification into the claims." 23 USPQ2d at 1017, citing *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430 (Fed. Cir. 1988), *cert. denied*, 109 S.Ct. 542 (1988).

71. *Bowles*, 23 USPQ2d at 1017.

72. *Id.*

73. *Id.* at 1017-18.

74. See *Adamo*, *supra* note 63, at p. 162-174.

fringement case before a court). In *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*,⁷⁵ the Federal Circuit was concerned with the language construction in product-by-process claims in the context of an infringement case.⁷⁶ The issue was whether process limitations stated in patent claims were to be treated in the same manner when interpreting the scope of the claims in both a patentability determination before the PTO or an infringement proceeding before a court, or were to be applied (or not) depending on the setting.⁷⁷

The Court in *Atlantic* supported the use of a double standard in which claim language would be read differently depending upon the context of the proceeding.⁷⁸ While this is significant, it is not clear if this reasoning can be carried over to the situation of deciding whether the statutory language contained in § 112, ¶6 is to be read literally when determining patentability.

The claims at issue in *Atlantic* contained specific language, which was either serving as a limitation on or was not being applied to limit the claimed subject matter. The claims were also of a particular type which has its own history of court interpretation. This argues for restricting the impact of *Atlantic* to the category of product-by-process claims.

The current means-plus-function language controversy can be viewed from several perspectives. In one sense, there is a disagreement between two branches of the government as to the appropriate interpretation of the actions of the third branch. The PTO is an administrative body, and hence part of the executive branch. Its duty is to implement the statutes passed by the legislature and signed into law by the chief executive. Its interpretative role is therefore limited. The Federal Circuit is a part of the judicial branch, specifically charged by Congress with bringing a measure of consistency to the operation of the patent laws. This favors the Court's interpretation of the statutory language.

However, it should be noted that the PTO position is not without merit. As Congress enacted and reenacted 35 U.S.C. § 112, ¶6 without modification, it is possible to view this as an implicit recognition of and agreement with the PTO's interpretation. Further, because *Lundberg* has not been explicitly overturned by an en banc decision of the Federal Circuit, the PTO can continue to maintain

75. 23 USPQ2d 1481 (Fed. Cir. 1992).

76. *Id.* at 1484-91.

77. *Id.* at 1490-91.

78. *Id.*

that there is no binding precedent which requires it to alter the manner in which it examines patent applications.

Another way to view the controversy is from the perspective of general principles of statutory interpretation. As statutes are generally to be interpreted in accordance with the ordinary, common meaning of their words, this argues for a literal application of the words of the statute. This would impose an explicit limitation on the scope of a means-plus-function claim, (i.e., the "corresponding structure, material, or acts described in the specification and equivalents thereof"). Such an interpretation would not, as the PTO suggests, place a burden on its examiners because the specification could be referred to as the source for any structure which would be used to bound the scope of the means language.

The issue would then relate to interpretation of the meaning of the term "equivalents". Is this term to be equated to its meaning in the doctrine of equivalents (or reverse doctrine of equivalents) sense, or does it have some other meaning? Is the equivalent meant to be a straight structural equivalent, or one determined by reference to the claimed function? One commentator has suggested that the inability of the PTO and the Court to agree that two meanings may exist for the use of the term "equivalents" is at the root of the problem.⁷⁹

It is also possible that the difference between the positions of the PTO and the Federal Circuit may end up being relevant only to the situation in which claims are being examined for purposes of determining whether they satisfy 35 U.S.C. § 101, (i.e., whether they claim statutory subject matter). This is supported by two recent decisions of the Board.⁸⁰ However, such a restriction of the context of the disagreement between the PTO and the Federal Circuit is not supported by the statutory language, or by the facts of *Iwahashi*, *Bowles*, and *Bond*.

The current disagreement between the PTO and the Federal Circuit may end up being resolved by a later decision in which the Court explicitly overturns *Lundberg* and sets the future course for how the language of § 112 is to be interpreted. It may also end up being addressed by Congress upon the next reenactment of the patent laws. This would allow Congress to make sure that the PTO's

79. See *Adamo* articles cited at n. 63.

80. See *Ex parte Akamatsu*, 22 USPQ2d 1915 (Bd. Pat. App. & Int. 1992) and *Ex parte Alappat*, 23 USPQ2d 1340 (Bd. Pat. App. & Int. 1992), both of which discuss the interpretation of the language of 35 U.S.C. § 112, ¶6 in the context of § 101 statutory subject matter determinations, and both of which curiously neglect any mention of *Bond* or the *Notice*.

interpretation of the statute is in conformity with the intended policies behind the patent laws. No matter what happens in the future, for the present time we are in the midst of a battle.

CONCLUSION

The doctrine regarding the patentability of algorithms has been refined but not substantially altered by the most recent Federal Circuit decision. The *Freeman-Walter-Abele* two-part test is still applied by both the PTO and the courts. The *Arrhythmia* decision further supports the idea of tying the operation of an algorithm to something physical, and confining it to a specific field of use in order to satisfy the § 101 inquiry. The disagreement between the PTO and the Federal Circuit as to the interpretation of § 112, ¶6 is more significant, at least for the present time. Whether it will remain so will depend upon the actions of the players.

COMMENTS

INTELLECTUAL PROPERTY LAW FOR REVERSE ENGINEERING COMPUTER PROGRAMS IN THE EUROPEAN COMMUNITY

Kathleen Gilbert-Macmillan*

TABLE OF CONTENTS

I. INTRODUCTION TO THE EC COUNCIL DIRECTIVE ON LEGAL PROTECTION OF COMPUTER SOFTWARE	249
A. <i>Purpose of the Directive</i>	249
B. <i>The Reverse Engineering Provision in Article 6</i>	251
II. HISTORY OF THE EC DIRECTIVE DEBATE	253
A. <i>Overview of the EC Legislative Process</i>	253
B. <i>Comparison of Opposing Positions on the EC Directive</i>	255
III. INTERPRETING THE REVERSE ENGINEERING PROVISION	257
A. <i>Terms of Article 6</i>	257
B. <i>Competing Products</i>	259
C. <i>Error Correction</i>	261
D. <i>Trade Secret Protection</i>	261
IV. PROPOSALS TO CLARIFY THE REVERSE ENGINEERING PROVISION	262
V. CONCLUSION	264

Copyright © 1993 by Kathleen Gilbert-Macmillan.

* Candidate, J.D. 1993, Santa Clara University School of Law; Ph.D. (Education), Stanford University; M.S. (Electrical Engineering), State University of New York at Stony Brook; B.A. (Mathematics), University of Colorado. The author gratefully acknowledges the following during the preparation of this Comment: the insightful guidance of Colin Tapper, All Souls Reader of Law and Vice-President of Magdalen College, Oxford University; valuable discussion with Frederick M. Gonzalez, Asst. Corporate Counsel at Amdahl Corp.; and generous encouragement from Howard C. Anawalt, Professor of Law, Santa Clara University.

INTELLECTUAL PROPERTY LAW FOR REVERSE ENGINEERING COMPUTER PROGRAMS IN THE EUROPEAN COMMUNITY

The European Community (EC) Council of Ministers finally adopted the controversial Directive on the Legal Protection of Computer Programs ("the Directive") on May 14, 1991.¹ Sparks flew during the last months of debate before the European Parliament's approval of the draft Directive.² The debate centered on the "decompilation," or "reverse engineering," issue.³ The reverse engineering of a computer program is a process by which the program's structure and code may be derived and analyzed.⁴ The program is unraveled to learn how it works. The knowledge gained may provide sufficient technical information to connect new software or hardware with the program, or to develop a similar program.

The Directive as adopted authorizes decompilation under limited conditions. As a result, European software producers may have greater access to the inner workings of American computer programs without the risk of facing an injunction aimed at preventing the European product from being marketed. For example, the Directive permits decompiling a computer program where reproducing the code is "indispensable" to figuring out how to connect a compatible product.⁵ Exactly what information is indispensable may be left to the interpretation of the courts in years to come when a product created with the help of reverse engineering analysis com-

1. Council Directive 91/250, 1991 O. J. (L 122) [hereinafter Council Directive].

2. The Directive attracted more debate and lobbying than any other item on the agenda for the program to establish a single European Market by the end of 1992. See Chris Reed, *Reverse Engineering Computer Programs Without Infringing Copyright*, 2 EUR. INTEL. PROP. REV. 53 (1991).

3. The terms "reverse engineering," "reverse analysis" and "decompilation" are often used interchangeably. It should be noted, however, that the definitions of the terms are not yet firmly established. Sometimes the term, "reverse engineering," is taken to mean a two-step process: reverse analysis plus forward programming. The reverse analysis step includes disassembling the program to analyze how it works. The forward programming step applies the analysis to building a new program. Interview with Frederick M. Gonzalez, Asst. Corp. Counsel & Chief Counsel Operations, Amdahl Corp., in Sunnyvale, CA (Dec. 15, 1992). Also see, Angelika Schnell & Anna M. Freska, SANTA CLARA COMPUTER & HIGH TECH. L.J. 59, 59 n.1 (1990).

4. Reverse engineering has been described as "software archaeology." It requires "extracting the software's functionality (what the software does) and the design (how it does it) by analysing the software's implementation - that is, programming code, data structures, files and databases." Alan Cane, FIN. TIMES, April 23, 1991, at 10, col. 1 (quoting Gilles Lafue).

5. Council Directive, *supra* note 1, art.1.

petes too fiercely with or replaces an established product in the marketplace.

The Directive is not effective law by itself; each member country of the EC must enact the terms of the Directive in its national laws.⁶ After the Directive is implemented and its effects have been assessed in practice, new provisions may be brought before the Commission to improve European law on the reverse engineering of software.

This comment reviews the purpose of the EC Directive and its reverse engineering provision. A brief review of the EC legislative process and an analysis of the lively debate on the Directive provides a background for the comment's discussion of issues in interpreting the reverse engineering provision. Finally, this comment suggests that the provision is too restrictive and permissible reverse engineering should be interpreted broadly.

I. INTRODUCTION OF THE EC COUNCIL DIRECTIVE ON LEGAL PROTECTION OF COMPUTER SOFTWARE

A. *Purpose of the Directive*

The goal of a single European market within the EC by 1993 increased the urgency to harmonize legislation among Member States' intellectual property laws. Differences in the laws of the various EC countries to protect computer programs have "direct and negative effects" on the functioning of the common market.⁷ Such differences are likely to continue without uniform laws among the Member States as they introduce new computer-related legislation.⁸ The inconsistent and, in some cases, absence of legislation protecting computer software across the EC has probably suppressed growth of the software industry in Europe. Commercial software sales in Europe have been substantial,⁹ but losses due to piracy of

6. If a directive has any direct effect on the law, it is only minor and depends on the degree to which national courts lean toward the language of the directive in interpreting existing law.

7. Council Directive, *supra* note 1, at 42. The lack of uniformity of legal protection for software discourages sellers of software to treat the EC as a large, single market. Countries with little or no protection for software are likely to be ignored altogether as good potential markets. The diffusion of high technology is then limited and the European economy as a whole may suffer.

8. *Id.*

9. Information technology spending in Europe, including hardware, software, services-maintenance systems, integration, and consulting has been estimated at more than \$140 billion in 1990. Freiburger, *U.S. High Tech Eyes Europe*, SAN FRANCISCO EXAMINER, Dec. 8, 1991, at E1, col. 6. In 1985 the Western European software market was estimated at \$9.5 billion with the sales of packaged software for personal computers growing at more than 30%

software have also been high.¹⁰ The Directive now provides a basis for uniform protection of computer programs in the EC. An analysis of the Directive and the surrounding controversy reveals an effort to find the delicate balance among the interests of large software companies, their smaller competitors, and users. At the center of the balancing act is the extent to which computer programs may be "reverse engineered" to create interoperable products. Large companies such as International Business Machines (IBM) prefer limited provisions for reverse engineering to protect their substantial foothold in the European computer market.¹¹ Smaller competitors, including European computer software companies, want broad rights to use reverse engineering in order to build systems and software to be compatible with the software of the giant computer companies.¹²

Traditionally, computer programs have been characterized as fitting more neatly into the subject matter of copyright than patent. Early programs were usually written in a textual form and appeared more similar to literary works, the subject of copyright law, than to useful inventions, the subject of patent law. In the United States, a Congressional study of the legal protection of software resulted in the proposition that computer programs should be protected under copyright statutes.¹³ Copyright seemed to afford the necessary protection with low cost.

Patent protection is expensive and more difficult to obtain. The impetus to restrict, even forbid, patent protection for computer programs came, ironically, from the United States in the late 1960s.¹⁴ Courts in the United States, however, have found it difficult to resolve copyright questions about protection of computer programs and computer companies have been seeking software pat-

per year. James Warnot, *Software Copyright Protection in the European Community: Existing Law and an Analysis of the Proposed Council Directive*, 6 SANTA CLARA COMPUTER & HIGH TECH. L.J. 355, 356 (1991) (citing *Green Paper on Copyright and the Challenge of Technology*, EUR. PARL. DOC. (COM NO. 88) 1, 171 (1988)).

10. It has been estimated that software manufacturers lost more than 4.5 billion dollars in 1989 due to piracy. See *Software Protection: EEC Adopts Directive*, Monthly Report on Eur., (Eur. Info. Serv.), § 3, at 7, (June, 1991). Such figures are highly speculative, however, and are calculated as if each "pirated" program would have been a sale. It is not clear that every copied program is equivalent to a lost sale.

11. See, e.g., A. B. Cleaver, *Reverse Engineering Could Be Misused*, FIN. TIMES, Sept. 17, 1990, at 19, col. 1.

12. See, e.g., Alan Cane, *Computer Users Fight EC Software Directive*, FIN. TIMES, Sept. 10, 1990, at 4, col. 1.

13. See NATIONAL COMM'N ON NEW TECHNOLOGICAL USES OF COPYRIGHTED WORKS, FINAL REPORT (1978).

14. COLIN TAPPER, *COMPUTER LAW* 9 (4th ed. 1989).

ents in the United States in growing numbers.¹⁵

Not foreseeing the difficulties with copyright protection, individual European countries quickly adopted the anti-patent stance promoted by the United States for computer programs.¹⁶ Article 1 of the EC Directive provides for protecting computer programs by copyright as literary works within the meaning of the Berne Convention.¹⁷ Copyright is the preferred form of protection in the EC because it is most consistent with the existing laws in the Member States and conforms to the trends among its trading partners.¹⁸

B. *Reverse Engineering Issue in Article 6*

Article 6 on "decompilation" (reverse engineering) did not appear in the initial drafts of the Directive. It first appeared formally in the Directive in the common position¹⁹ adopted by the Council a few months before final adoption after intense lobbying and debate. Decompilation of a computer program under the Directive is permitted without authorization when it is "indispensable to obtain the information necessary to achieve the interoperability of an independently created computer program with other programs" under some limiting conditions. Those conditions include that: (i) the reverse engineering be performed by the licensee; (ii) the information necessary to achieve interoperability has not previously been readily available to the licensee; and (iii) the reverse engineering will be confined to the parts of the program necessary to achieve interoperability.²⁰ Reverse engineering is not to be used for goals other than to achieve interoperability of the independently created program. Neither is it permitted for reverse engineering to be used for the development of any computer program "substantially similar in its expression, or for any other act which infringes copyright."²¹

There has been controversy over the meaning of "interoper-

15. See, e.g., John H. Barton, *Adapting the Intellectual Property System to New Technologies*, (Dec. 13, 1991) (paper prepared for the Nat'l Res. Council Conference on the Global Dimensions of Intellectual Property Rights in Science and Technology, Wash. D.C., Jan. 8-9, 1992).

16. TAPPER, *supra* note 14, at 9.

17. The Berne Convention is a series of acts, not a single document. Most EC Member States adhere to the Paris Act of 1971, reprinted in 4 M. NIMMER & D. NIMMER, *NIMMER ON COPYRIGHT* app. 27 (1988).

18. Commission Proposal for a Council Directive on the Legal Protection of Computer Programs, pt. 1(3.6), 1989 O.J. (C 91/4) 5, 7.

19. The common position is the draft form of the proposal which the Council of Ministers is willing to adopt before the draft is returned to the European Parliament for a second reading. See discussion *infra* part II.A. for an overview of the EC legislative process.

20. Council Directive, *supra* note 1, art. 6(1).

21. *Id.*, art. 6(2).

ability." The Directive defines "interoperability" as "the ability to exchange information and mutually to use the information which has been exchanged."²² Whether or not this means reverse engineering can be allowed for creating replacement products, not merely attaching or "interfacing" products, was much debated. An attempt to clarify the issue was made by a communication to the European Parliament from the Commission: "Decompilation is permitted by Article 6 to the extent necessary to ensure the interoperability of an independently created computer program. Such a program may connect to the program subject to decompilation. Alternatively it may compete with the decompiled program and in such cases will not normally connect to it . . ."²³ In other words, decompilation *may not* be used to reproduce pieces of a program that are unrelated to the interoperability of the original program. However, decompilation *may* be used to create a competing program as long as the only "reverse engineered" parts of the original program are those that affect the program's interfaces with other programs and computer systems.²⁴

A goal of Article 6, in its attempt to loosen restrictions on decompilation, is to move the EC in the direction of open systems.²⁵ Open systems, in the broad sense, provide the capability to use the same software on different kinds of computers and to exchange data on a wide variety of computer networks.²⁶ Yet in reality, the narrowness of the Directive's provisions and the tight circle drawn around permissible reverse engineering only for purposes of interoperability may have only a minor effect on the EC's movement

22. *Id.*, at 43.

23. SEC 91 final - SYN 183, *quoted in* Mark Powell, 8 *COMPUTER LAW* 13, 16 (1991). Further support was given to the interpretation that reverse engineering may be used both for attaching and competing products during a conference on the Directive in March, 1991. H. C. Overbury, Head of the Merger Task Force, said in a speech, "The Commission believes that where necessary . . . it will be possible for competitors to extract interface information which is not covered by copyright by analysis techniques so as to develop interoperable products. These interoperable products may be attaching products or they may be competing products." *Id.*, fn. 12 at 15.

24. *See, e.g.*, Thomas C. Vinje, *The Development of Interoperable Products Under the EC Software Directive*, *COMPUTER LAW*, Nov. 1991, at 1, 6.

25. BRIDGET CZARNOTA & ROBERT J. HART, *LEGAL PROTECTION OF COMPUTER PROGRAMS IN EUROPE* 34 (1991). The term, "open systems," is used here in the non-proprietary sense.

26. The definitions of "open systems" vary according to the provider of the definition. A starting point, however, may be the definition from the Institute of Electrical and Electronic Engineers: "[Open systems are] a comprehensive and consistent set of international information technology standards and functional profiles that specify interfaces, services and supporting formats to accomplish interoperability and portability of applications, data and people." *Quoted in* IBM SYTEM USER, Feb., 1992, Vol. 13, No. 2 at 37.

toward becoming a development center and marketplace for open systems. The proposal in this Comment is for a broad interpretation of the Directive's Article 6 provisions to encourage technological developments for the support of open systems.

II. HISTORY OF THE EC DIRECTIVE DEBATE

A. *Overview of the EC Legislative Process*

Twelve Western European countries are Member States of the European Economic Community.²⁷ The Community is governed by five institutions: the European Commission, Council of Ministers, European Council, European Parliament, and the European Court of Justice. The Commission proposes legislation to the Council of Ministers to implement as treaties. The Commission is also to ensure proper implementation of the Directives adopted by the Council of Ministers. If a Member State fails to implement a Directive correctly or in time with its own national legislation, the Member State may be called before the European Court of Justice for treaty violations.

The Commission formally initiates the legislative process and submits an initial proposal to the Council of Ministers whose members are appointed by their respective national governments. After the Council comes to an agreement on the proposal, it is reviewed, debated, possibly amended, and written as draft legislation. The European Parliament may recommend to adopt the draft and it is returned to the Commission. The Commission then presents a modified proposal to the Council. The Council works to reach a common position, the draft form of the proposal the Council is willing to adopt. This draft is returned to the Parliament for a second reading. Parliament returns its final recommendations for adopting, rejecting, or amending the common position so that the Council can officially adopt or reject the proposal. If the Parliament rejects the common position, a unanimous vote by the Council is required to pass the legislation.²⁸

In June, 1988 the Commission published the 237-page Green

27. The European Economic Community was established under the Treaty of Rome, Mar. 25, 1957, art. 2, 298 U.N.T.S. 11, 15. The current Member States are Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain and the United Kingdom.

28. See *EC Institutions and the Decision Making Process*, EUROSCOPE, (Coopers & Lybrand) (Jan. 9, 1992).

Paper on Copyright.²⁹ Chapter 5 of the Green Paper is concerned with the protection of copyright in computer programs. It emphasizes the economic importance of computer software, the present dominance of the U.S. firms in the world software market, and the need for appropriate legal protection for software to encourage investment and innovation by Community firms, permitting the Community industry to catch up with its competitors.³⁰

The Green Paper called for, as a matter of urgency, a proposal for a directive for the protection of computer programs. After a public hearing and replies to its questionnaire, the Commission submitted its first proposal in December, 1988.³¹ The Economic and Social Committee, with few comments, gave overall approval to the draft.³² Although the reverse engineering issue was heavily debated at this time, the draft was devoid of specific language on the topic. It was at least arguable, however, that reverse engineering would be prohibited.³³ A milestone in consideration of the Directive was achieved in July, 1990 when the European Parliament completed its first reading and adopted numerous amendments to the Directive.³⁴

A revised draft of the proposal was submitted by the Commission in October, 1990³⁵ and a common position was adopted by the Council in that same year. Language was included that more clearly would permit limited decompilation. The common position was the form in which the Council was prepared to adopt the legislation. In April, 1991, the proposed Directive received its second reading by the European Parliament. Eleven amendments to the common position were proposed. The amendments were intended to broaden the scope of the Directive for research and analysis, as well as to clarify the status of interfaces under copyright law. The leading advocate promoting adoption of the amendments was the European Committee for Interoperable Systems (ECIS), a group of

29. Green Paper on Copyright and the Challenge of Technology - Copyright Issues Requiring Immediate Action, EUR. PARL. DOC. (COM 88) 1, 172 (1988).

30. *Id.*

31. Proposal for a Council Directive on the Legal Protection of Computer Programs, 1989 O.J. (C 91) 4 (1989).

32. Opinion on the Proposal for a Council Directive on the Legal Protection of Computer Programs, 1989 O.J. (C 329) 4 (1989).

33. Harry Small, The Draft Directive on the Protection of Computer Software 19 (Oct. 15, 1990) (paper presented at the Computer Law Sect. of the Santa Clara County Bar Assoc. & the Santa Clara Univ. School of Law International Protection of Computer Technology Seminar).

34. Colombe & Meyer, *Interoperability Still Threatened by EC Software Directive: A Status Report*, 9 EUR. INTELL. PROP. REV. 325, 325 (1990).

35. Amended Proposal for a Council Directive on the Legal Protection of Computer Programs, 1990 O.J. EUR. COMM. (C 320) 22.

computer companies in favor of authorizing extensive reverse engineering of software.³⁶ However, the amendments failed to get sufficient votes in the European Parliament and the Council formally adopted the common position in May, 1991. EC Member States are required to enact legislation in compliance with the Directive before January 1, 1993.³⁷

B. *Comparison of Opposing Positions on the EC Directive*

The controversy during the passage of the Directive centered on two related provisions of the first draft: protection of interfaces and the prohibition of reverse engineering.

1. Interfaces

The Directive defines interfaces as the parts of the program which provide for the interconnection and interaction between elements of software and hardware.³⁸ A goal of the Commission, stated in the Green Paper, is to encourage interoperability within and among computer systems. A prerequisite to interoperability is open interfaces, that is, published, freely available specifications or documentation containing the information required to be able to connect to or interact with the computer systems. The first draft of the Directive gingerly gave access to interfaces by making interoperability an exception to general copyright rules, but the language was still cloudy.³⁹ The final Directive substituted new language which effectively removed some doubt, but pressure through groups like the Business Software Association (BSA), a group of business software producers and SAGE, a group of primarily American hardware manufacturers, resulted in a narrower scope of allowable access to interfaces.⁴⁰

Groups such as BSA and SAGE who wanted to prohibit analysis of interfaces argued that opening the access to interfaces and exempting these parts of computer programs from copyright protection would harm the software industry.⁴¹ They claimed that an exception for interfaces could not be clearly drafted and so would

36. Cane, *supra* note 4.

37. Council Directive, *supra* note 1, art. 10(1). *Also see supra* note 6.

38. Council Directive, *supra* note 1, at 43.

39. W. R. Cornish, *Inter-operable Systems and Copyright*, 11 EUR. INTELL. PROP. REV. 391, 391 (1989).

40. *See, e.g.*, Colombe & Meyer, *supra* note 34.

41. *See, e.g.*, William T. Lake, John H. Harwood II, and Thomas P. Olson, *Seeking Compatibility or Avoiding Development Costs? A Reply on Software Copyright in the EC*, 12 EUR. INTELL. PROP. REV. 431 (1989).

result in permission to copy the detailed expression of a successful program. They argued further that the real issue raised by the exemptions for interfaces, as well as reverse engineering, was whether easy cloning should be allowed under EC copyright law. In their view, the present system works well without exempting interfaces from copyright protection: the software industry is flourishing and access to interfaces, while often available by industry choice, is not a legislated exemption under the law of any country.⁴²

Others, primarily represented by ECIS and smaller European computer firms, argued that the Directive should state that the specification of interfaces to computer programs are exempt from protection under copyright law. "The majority of people in the industry, as well as computer users throughout Europe, will be best served by clear language in the Directive that authorises use of specifications underlying program interfaces and permits reverse analysis of existing computer products"⁴³ The final Directive has clarified that ideas underlying an interface are exempt from copyright protection. However, the formulation contained in the Directive is general and producing a clone without infringing the copyright in the original may still be difficult.⁴⁴

2. Reverse Engineering

Reverse engineering is the second major issue that dominated debate on the Directive. It is also the issue that continues to be a primary source of uncertainty concerning future application of the new legislation. Under the first draft of the Directive, reverse engineering was essentially prohibited. Those in favor of providing an exemption for decompilation included the ECIS led by Fujitsu, the Japanese computer manufacturer. They argued that without such an exemption, it would be impossible for competitors to develop competing software products since it is necessary to understand how a program functions before one can develop a competitive program, or software that will interact with the original program.⁴⁵

Another argument in favor of permitting decompilation is that decompiling computer programs is merely the discovery of rules essential in the process of original programming.

42. *Id.* at 431, 432.

43. Colombe & Meyer, *Seeking Interoperability: An Industry Response*, 3 EUR. INTELL. PROP. REV. 79, 82-3 (1990).

44. Chris Reed, *Reverse Engineering Computer Programs Without Infringing Copyright*, 2 EUR. INTELL. PROP. REV. 47, 53 (1991).

45. Small, *supra* note 33, at 19.

[Decompilation] is not a procedure for picking apart a complex object into its elements, so that each may be imitated and the whole copied in an exact or closely similar imitation. Nor is it even an identification of the elements of a product so that they may be adapted in some improved way to a new end. It is simply the discovery of the rules which have to be complied with when the independent producer constructs his own program.⁴⁶

Arguments against this position, supported by BSA and SAGE, include the following: (i) permitting reverse engineering would be a dramatic change from existing law; (ii) reverse engineering is unnecessary to develop interoperable products because manuals and other documentation can be used; (iii) imitation programs could be reproduced at much lower costs than the original; and (iv) legalizing reverse engineering would dramatically reduce the lead time that motivates investment in new software.⁴⁷

In adopting the final Directive, the Council voted in favor of reverse engineering provided that: (i) it is performed by the licensee; (ii) the information necessary to achieve interoperability has not previously been readily available to the licensee; and (iii) the reverse engineering will be confined solely to the parts of the program necessary to achieve interoperability.⁴⁸ The Directive prohibits any information acquired from permissible reverse engineering to be used for any goal other than to achieve interoperability. Perhaps reflecting the lobbying efforts of groups such as SAGE, reverse engineering cannot be used in the development of any competing product.

III. INTERPRETING THE REVERSE ENGINEERING PROVISION

A. *Terms of Article 6*

Article 6 of the Directive is under the heading "Decompilation" and states its terms as follows:

46. Cornish, *supra* note 39, at 391.

47. Lake *et al.*, *supra* note 41. It has been suggested that authorizing reverse engineering would discourage software developers from investing in the creation of new programs. The argument is that "the prospect of almost immediate competition from an unconsented adaptation of his own work - which could be sold cheaply because the imitator bore little development expense" might be sufficient to discourage "[especially] newer and smaller developers." *Id.* at 434. Perhaps, however, prohibiting reverse engineering is more likely to prevent development of new products by smaller developers because they are forbidden to do research and analysis to create products that would otherwise have been interoperable. In reality, manuals and other written materials that fully and accurately document interface information are rarely available.

48. Council Directive, *supra* note 1, art. 6.

1. The authorization of the rightholder shall not be required where reproduction of the code and translation of its form . . . are indispensable to obtain the information necessary to achieve the interoperability of an independently created computer program with other programs, provided that the following conditions are met:

(a) these acts are performed by the licensee or by another person having a right to use a copy of a program, or on their behalf by a person authorized to do so;

(b) the information necessary to achieve interoperability has not previously been readily available to the persons referred to in subparagraph (a); and

(c) these acts are confined to the parts of the original program which are necessary to achieve interoperability.

2. The provisions of paragraph 1 shall not permit the information obtained through its application:

(a) to be used for goals other than to achieve the interoperability of the independently created computer program;

(b) to be given to others, except when necessary for the interoperability of the independently created computer program; or

(c) to be used for the development, production or marketing of a computer program substantially similar in its expression, or for any other act which infringes copyright.⁴⁹

Although the terms of Article 6 authorize some reverse engineering, the range of permissible purposes is narrow. Reverse engineering may be used to extract information necessary to interface one program to another, but not for developing any computer program that would be so similar as to result in a copyright infringement. "In practical terms, . . . it would be permissible to reverse engineer Microsoft MS-DOS to produce a properly engineered IBM PC compatible . . . application, but not in order to produce an IBM compatible . . . operating system (although it would be possible to reverse engineer the IBM BIOS [basic input-out system] to do that)."⁵⁰

Although some people fear that any degree of permissible reverse engineering will harm the owners of the original program, the Directive provides those owners substantial protection. The owners of the copyright in the original program are protected against the reverse engineering of that program by anyone who has not bought or licensed it. Furthermore, the Directive permits reverse engineer-

49. *Id.*

50. Small, *supra* note 33, at 20.

ing only when the information necessary to achieve interoperability has not already been made available.⁵¹ The original developer can prevent reverse engineering of the program by making the information necessary to achieve interoperability readily available to the buyer or licensee. An underlying problem, however, is the determination of the factual question concerning what and how much information is necessary for a software developer to build an interoperable program. It is not clear whether or not the standard should be different for a small independent software producer as compared to a large multinational computer company with sophisticated technology. Also unclear is who decides whether the interface information is sufficient, accurate and up-to-date. These unanswered questions point to a potentially significant weakness of the Directive.

The Directive emphatically protects the rightholder from misappropriation of software by disallowing reverse engineering to be used for any goal other than to achieve interoperability of the independently created computer programs.⁵² As if to underscore that provision, two paragraphs later the Directive states that reverse engineering shall not be used for developing, producing or marketing any program⁵³ substantially similar to the original program.

B. *Competing Products*

One of the chief concerns about Article 6 is that the strict control of reverse engineering could result in limiting the supply of competitive products and seriously harm computer users' ability to maintain and integrate systems.⁵⁴ Small software developers are likely to be the most reluctant to undertake the reverse engineering necessary for them to develop similar competing products. They can least afford the risk of protracted litigation to clarify whether their reverse engineering was, for example, "confined to the parts of the original program which [were] necessary to achieve interoperability" or "used for goals other than to achieve the interoperability of the independently created computer program."⁵⁵ Although it appears that Article 6 allows reverse engineering in order to develop noninfringing competing products, the reverse engineering is limited to the parts of the original program related to the interface.

51. Council Directive, *supra* note 1, art. 6(1)b.

52. Council Directive, *supra* note 1, art. 6(2)a.

53. Council Directive, *supra* note 1, art. 6(2)c.

54. Dom Pancucci, *Computer Users Europe Group Aims and Objectives*, PC USER, June 5, 1991, at 27, col. 1.

55. Council Directive, *supra* note 1, art. 6(1)b.

The interfaces of computer programs are rarely neatly defined. Paradoxically, it may be difficult or impossible to determine which parts of a computer program are technically necessary to achieve interoperability, hence permissible for reverse analysis, without a full analysis of the entire program.

Competition can encourage innovation in technology.⁵⁶ Restricting reverse engineering to only the purpose of obtaining interface information will limit the diffusion of ideas and principles underlying the original program. The Directive allows users of computer programs to "observe, study or test the functioning of the program in order to determine the ideas and principles which underlie any element of the program if he does so while performing any of the acts of loading, displaying, running, transmitting or storing the program which he is entitled to do."⁵⁷ Denying the user the right to engage in reverse engineering to study the ideas and principles underlying the program as a whole may reduce innovation and inhibit competition.

Although reverse engineering is permitted for developing independently created software under the constraints of Article 6, there is no explicit extension to applying the same reverse engineering to the development of hardware. The recitals preceding Article 1 of the Directive expressly refer to hardware, however, in defining interoperability:

Whereas the parts of the program which provide for such interconnection and interaction between elements of software and hardware are generally known as 'interfaces';

Whereas this functional interconnection and interaction is generally known as 'interoperability'; whereas such interoperability can be defined as the ability to exchange information and mutually to use the information which has been exchanged;⁵⁸

It is therefore sometimes argued that independently created hardware may be produced as a result of information learned through reverse engineering authorized under Article 6.⁵⁹ On the other hand, it is argued that the permitted reverse engineering pertains only to the creation of the interconnecting software and not to the *creation* of new hardware.⁶⁰ Ultimately, then, the issue of whether or not new hardware may be built by utilizing information acquired

56. For example, the rapid development of IBM personal computer products is largely attributable to the widespread activity of IBM clone-makers.

57. Council Directive, *supra* note 1, art. 5(3).

58. *Id.* at 43.

59. Powell, *supra* note 23, at 15.

60. CZARNOTA & HART, *supra* note 25.

through decompilation of software may be left to either the courts or to the standards and customs of the industry.

C. *Error Correction*

Translating, adapting, or otherwise altering a computer program to correct errors in the program where necessary for the use of the program is permitted by the Directive without authorization of the rightholder in the absence of contractual provisions to the contrary.⁶¹ It appears then that the decompilation restrictions of Article 6 do not apply to error correction. What constitutes an error under the Directive, however, is unclear. The user may identify a behavior of a program as an error, while the owner may define the behavior as an intended feature. The effect may be to diminish the limitations of the decompilation provisions as long as the user can show that reverse engineering was "necessary" for the intended use of the program.

D. *Trade Secret Protection*

Article 6 does not override "any other legal provisions such as those concerning patent rights, trade-marks, unfair competition, trade secrets, protection of semi-conductor products or the law of contract."⁶² A software company might then claim that it could protect a given program against reverse engineering through a contract with the licensee preventing the licensee from disclosing or using any trade secret of the licensor. While the licensee could derive information about the program under Article 6, in this example, the software company's interpretation of the Directive implies that the licensee could not use that information. Such a result would be contrary to a stated objective in the Directive: "to make it possible to connect all components of a computer system, including those of different manufacturers, so that they can work together."⁶³ Article 9(1) of the Directive provides that any contract contrary to the provisions of Article 6 shall be deemed null and void under the Directive.⁶⁴ The Directive must then be interpreted to mean that contractual restrictions based on trade-secret protection cannot be used to retain exclusive rights to the interface information which

61. Council Directive, *supra* note 1, art. 5(1).

62. *Id.*, art. 9(1).

63. Council Directive, *supra* note 1, at 43.

64. *Id.*

may legitimately be obtained without infringement.⁶⁵

IV. PROPOSALS TO CLARIFY THE REVERSE ENGINEERING PROVISION

It is usually difficult to prove that reverse engineering has been performed on a computer program unless an infringing copy is produced. In that case, the law of copyright suffices and one may question the need for Article 6 of the Directive. Typically intellectual property law does not prohibit the study and analysis of the ideas and principles of the underlying product, even for those who intend to create competing products.⁶⁶ The strongest protection is given by patent law where all the underlying ideas are disclosed to the public after a strict review to verify that the invention is novel and non-obvious.⁶⁷ The law of trade secrets clearly allows the analysis of ideas once the secrets have been learned by another without a breach of confidence. Reverse engineering is a likely way to gain that knowledge. Neither does the law of copyright, as applied to works other than computer programs, prevent the study of the work's underlying ideas and principles. A person may read and analyze all the ideas in a book for the purpose of creating a competing work as long as she does not infringe the expression in the original book. Computer programs under the EC Directive appear to be the sole exception to these general intellectual property law principles.⁶⁸

A better policy might be to revise Article 6 to permit reverse analysis to study the underlying ideas and principles of a computer program so long as an infringing product is not produced. Such a provision could be similar to the reverse engineering allowed in the semiconductor field by the Semiconductor Chip Act of 1984.⁶⁹ This legislation legitimized "the general industry practice of 'reverse engineering' whereby existing chips were improved upon enough to constitute original new designs."⁷⁰

The Directive is unclear as to whether new, independently created hardware may be developed from information acquired

65. Thomas Dreier, *The Council Directive of 14 May 1991 on the Legal Protection of Computer Programs*, 9 EUR. INTELL. PROP. REV. 319, 325 (1991).

66. See, e.g., *SEGA Enterprises v. Accolade, Inc.*, No. 92-15655, 1993 U.S. App. LEXIS 78, at 27 (9th Cir. Jan. 6, 1993). The court stated that "[w]here there is a good reason for studying or examining the unprotected aspects of a copyrighted computer program, disassembly for purposes of such study or examination constitutes a fair use."

67. 17 U.S.C. §§ 102, 103 (1988).

68. Colombe & Meyer, *supra* note 34, at 327-8.

69. 17 U.S.C.A. §§ 901-914 (1984).

70. TAPPER, *supra* note 14, at 43.

through the reverse engineering of software.⁷¹ Contrary to arguments that it is inappropriate to permit software reverse engineering in order to create new hardware,⁷² this Comment proposes adding specific language to the Directive in support of allowing reverse engineering for the purpose of building new, interconnecting hardware. Often the technological line between software and hardware is blurry, if not invisible. The addition of language permitting hardware development based on software interface decompilation would simply remove concerns about that blurry line. Such language would also expand the possibilities for applying existing information about particular software interfaces to new technological developments in hardware.

Software developers who choose not to make interface information available under the terms of the Directive face the risk of their products being reverse engineered by competitors. But the Directive does not make it clear whether or not the information must be made *freely* available or if the developer can charge the licensee specifically for the interface specifications. It has been suggested that if the licensee refused to pay for the information, the original developer could protect its rights in the program against reverse engineering.⁷³ This interpretation appears to run counter to the intention of the Directive to encourage interoperable systems. If original developers are permitted to charge for interface information, the exemption for reverse engineering in Article 6 is potentially vacuous. A better interpretation would be that if original developers do not freely make interface information available, they run the risk of their products being decompiled by others. The alternative is for the developer to make enough information available so that another programmer can write interface software to be fully interoperable with the original program. The right of the developer to charge money for the interface information should be specifically and vehemently denied in the Directive and in the implementing legislation in order to protect the fundamental intent of Article 6 in favor of interoperable systems.

However, Article 6, as finally adopted in the Directive, has been the subject of vigorous long-term debate and compromise. It is unlikely that the Directive will be rewritten in the near future. Instead, as Member States write their own legislation to implement

71. See *supra*, part III.B.

72. CZARNOTA & HART, *supra* note 25.

73. Hilary Pearson, Clifford Miller & Nigel Turtle, *Commercial Implications of the European Software Copyright*, COMPUTER LAW, Nov. 1991, at 13, 17.

the Directive as it stands, they should clarify some of the general and uncertain sections with more specific language. At the same time, wide latitude should be given for study and analysis of the underlying ideas and principles of computer programs. For example, the condition of "necessity" required in Article 6 to conduct reverse engineering should be taken to mean "reasonable necessity." As written, the provision requires reverse engineering to be "confined to the parts of the original program which are *necessary* [emphasis added] to achieve interoperability."⁷⁴ "Necessary" should be rewritten, or interpreted, to mean "reasonably necessary." Otherwise, in those cases where it is discovered later that a particular well-intended reverse analysis was not necessary to achieve interoperability, the court may lack flexibility to apply an appropriate standard.

Finally, as the Directive is implemented and interpreted, the technology of computer programs will continue to change and introduce new complexities. Each Member State, its legislature and courts, should strive to balance their national goals with both the competition and protection required for technological progress in the EC and globally.

V. CONCLUSION

The Directive has been praised as finding a balance among the interests and needs of the market leaders in the computer industry, those who depend on information about the interfaces of the market leaders' products, and legitimate program users.⁷⁵ Despite some difficulties with general wording and uncertain terms, the expected result is that soon there will be uniform protection of computer programs throughout the EC. European software producers may be better able to compete with the market leaders as a result of the opening of interfaces to reverse engineering. The price the market leaders will have to pay appears slight and they will receive the benefits of widespread copyright protection for their software throughout Europe.

74. Council Directive, *supra* note 1, art. 6(1)c.

75. Dreier, *supra* note 65, at 319.

INDONESIA'S NEW PATENT LAW: A MOVE IN THE RIGHT DIRECTION

Fabiola M. Suwanto*

On November 1, 1991, the Indonesian Parliament passed Law No. 6/1989 on Patents. With that, Indonesia obtained her first patent law since her independence in 1945. This new law came into effect on August 1, 1991. Law No. 6/1989, containing sixteen sections and one hundred and thirty-four articles, is the government's most earnest attempt to cast off Indonesia's image as one of the world's worst protectors of intellectual property. This long-awaited occasion was welcomed by many foreign countries and local businesses. However, several questions that should be asked are, how tight are the laws? Will they be sufficient to create the economic climate suited to the demands of foreign investors seeking to invest in Indonesia? Can the laws be implemented adequately so as to provide effective protection?

This comment examines these issues in the following manner. First, the need for a new patent law will be spelled out. The forces, which drove the Indonesian government to institute the laws, will also be discussed. Second, some of the sections and articles of the patent law will be reviewed. Third, the comment will probe into the most recent implementing regulations and decrees that address portions of the patent law. Several controversial areas, which are still causing debate, as well as confusion, will be examined to facilitate a fuller appreciation of the problems surrounding the protection of intellectual property in Indonesia. Fourth, some of the ways the Indonesian government is trying to prepare for the successful implementation of the system will be highlighted. Two potential methods which may help in this aspect will also be suggested. Finally, this comment will speculate as to the probability of the patent law accomplishing its purposes.

I. INTRODUCTION: THE NEED FOR A NEW PATENT LAW

Indonesia was a colony of The Netherlands since the 1600s.

Copyright © 1993 by Fabiola Suwanto.

* J.D./M.B.A. 1992 Santa Clara University. B.A. 1988 Phillips University. The author thanks her family for their support.

Although Indonesia gained her independence in 1945, The Netherlands did not officially declare the "United States of Indonesia" as an independent nation until 1949.¹ In the interim, the Colonial Government ratified the London version of the Paris Convention for itself and on the behalf of Indonesia as well.²

When Indonesia finally emerged as a new state, it had to determine the status of the colonial acts on intellectual property. The Dutch Patent Act which was enacted in July 1912 was discontinued because it required that inventions be materially examined in The Netherlands.³ This was in conflict with the sovereignty of an independent nation.⁴ A ministerial regulation on patent application registration was made on August 12, 1953.⁵ In that regulation, the Minister of Justice proclaimed that a patent act was to be enacted soon. As of November 1, 1953, anyone wishing to obtain a patent was to file his application with the Ministry of Justice.⁶ Unfortunately, the awaited patent act never materialized. As of 1989, there have been over 13,000 applications for temporary patent registration, 96% of which were of foreign origins.⁷ None of the applications, foreign and local alike, were ever granted because no patent law existed.⁸

Indonesia also had to deal with the status of her membership to the Paris Convention after her independence. Sources conflict on this issue. One source claims that "(f)ollowing independence, the Indonesian Government declared in 1950 that Indonesia considered itself to be the legal successor of the Dutch East Indies and therefore bound by this Convention."⁹ Another source states that Indonesian judges, "without further examining the relevant questions of

1. Christoph Antons, *The Development of Intellectual Property Law in Indonesia: From Colonial to National Law*, (unpublished draft, on file with the author).

2. *Id.*

3. J.B. Lumenta, *Indonesia Plans to Update Its Patent Law*, JAKARTA POST, Aug. 1, 1989, at 4.

4. Elisabeth Uphoff, *Intellectual Property Protection and the U.S. Relations with Singapore, Malaysia, Indonesia and Thailand*, written for the Southeast Asia Program, Cornell University, Dec. 1988.

5. Christoph Antons, *supra* note 1.

6. Duane J. Gingerich, *Indonesia*, E. ASIAN EXECUTIVE REP., Vol. 11, No. 12, Dec. 15, 1989 at 9.

7. Duane J. Gingerich, *New Patent Law Under Discussion*, IP ASIA, Aug. 10, 1989, at 13.

8. Only applications filed within 10 years of the effective date, i.e. August 1, 1981, can be re-registered under the new patent law. See Duane J. Gingerich, *New Patent Law*, IP ASIA, Nov. 22, 1989, at 18.

9. Christoph Antons, *Intellectual Property Law in ASEAN Countries: A Survey*, 3 EIPR 78, 82 (1991).

public international law, regard the declaration of the Dutch concerning the Paris Convention of 1948 as not binding on Indonesia. Consequently, membership of the Paris Convention is denied, although in fact only ratification of the London Revision can be disputed."¹⁰ This matter is yet to be clearly resolved.

In 1958, Indonesia withdrew itself from the Berne Convention, one of the oldest multilateral copyright conventions.¹¹ Former President Sukarno claimed that it was beyond Indonesia's capability to pay royalties.¹² The country needed a relatively inexpensive way to make goods it could sell to obtain revenue. Making copies of foreign goods was convenient and lucrative.¹³ The protection of intellectual property was not an immediate concern. Before long, Indonesia was equated with being the haven for piracy, the nightmare of foreign investors. It had been alleged that in 1986, United States companies lost 210 million U.S. dollars because of the pirating of software technology alone that went on in Indonesia.¹⁴ It was also reported that pirated music cassettes, videotapes, pharmaceuticals and computer software were prevalent in the country and were big money makers.¹⁵

An example of counterfeiting may be helpful to understand the frustrations experienced by investors whose patent rights have been infringed. It should be noted however, that this example is a rare and extreme one. Company X was a pharmaceutical company which had discovered that its product had been copied and sold in Indonesia.¹⁶ Its Managing Director claimed that the counterfeit was so good that had they not analyzed the tablets, they would not have known the difference. An analysis of the counterfeit revealed that it had a smaller amount of the "active ingredients" found in a genuine tablet. This meant that the production costs of the counter-

10. Christoph Antons, *supra* note 1.

11. *Indonesia to Enhance Copyright Protection, but Enforcement is Key*, BUSINESS INTERNATIONAL, Vol. XIX, No 31, August 3, 1987. The International Union for the Protection of Literary and Artistic Works (also known as the Berne Convention) was first established in 1886 in Berne, Switzerland. The Convention requires protection be given to works, published or unpublished, of an author. See Marshall A. Leaffer, UNDERSTANDING COPYRIGHT LAW, LEGAL TEXT SERIES (1988).

12. *Indonesia to Enhance Copyright Protection*, *supra* note 11.

13. *Id.*

14. *New Laws Will Better Protect Intellectual Property Rights of Foreign Firms*, MULTINATIONAL STRATEGIES, COUNTRY MONITORING SERVICE, Aug. 1987.

15. *Licensing — General; Patent and Trademark Protection*, BUSINESS INTERNATIONAL, INVESTING, LICENSING & TRADING, January, 1988. See also U.S., *Indonesia in Agreement to End Copyright Piracy*, REUTERS, Mar. 22, 1989.

16. This information was obtained through an interview in Jakarta, Indonesia, with a gentleman who requested that his name be withheld.

feit were less. The company attempted to deal with the counterfeit problem but eventually decided to pull its investments out of Indonesia.¹⁷ This unpleasant experience was costly to both the foreign investor as well as the country of Indonesia.

It is unfortunate that the very things which allowed Indonesia to make money were those which caused companies in the United States and other countries to take significant losses.¹⁸ Not surprisingly, the United States and the European Economic Community (EEC) retaliated. They threatened to withdraw the trade benefits they had been granting Indonesia unless Indonesia revamped its current intellectual property laws.¹⁹ This caught the attention of the Indonesian government. On September 9, 1987, the Indonesian Parliament finally passed amendments to the 1982 Copyright Law.²⁰ March 1988 saw the signing of a treaty between Indonesia and the United States which covers all copyrights.²¹ In that treaty, both countries agreed to give foreign artists the same protection their native artists would have in their own native lands.²² On May 27, 1988 Indonesia agreed with some of the EEC countries to end piracy of audio cassettes.²³ Pirated cassettes of foreign music were to be cleared off the shelves by June 1988.²⁴ That agreement was successful in substantially decreasing the amount of pirated goods in the consumer market.²⁵ While these were important steps towards affording better protection to intellectual property, a revised copyright law alone would not suffice. Foreign governments pushed for the reform of trademark laws and the establishment of patent laws as well.

II. FACTORS WHICH LED INDONESIA TO ESTABLISH THE NEW PATENT LAW

Several important factors finally resulted in Indonesia's enactment of the patent laws. Indonesia recognized that poor protection

17. The company hired people to locate the places which sold the counterfeit products. While they were able to seize the products, they were unable to identify the suppliers. The company refused to sustain such losses and decided to close down its operations in Indonesia.

18. Jacques J. Gorlin, *Yo, Ho, Ho, and a Gucci Bag*, *WORLD PAPER*, Mar. 1989, at 1.

19. See *Licensing — General; Patent and Trademark Protection*, *supra* note 15.

20. *Id.*

21. Matthew Shears, *Shops Clear Pirated Software from Shelves as U.S.-Indonesia Treaty Goes Into Effect*, *PR Newswire*, Aug. 2, 1989.

22. *Id.*

23. Mochtar Lubis, *How Retaliation Works; Indonesians Face the Music After European Threat*, *WORLD PAPER*, Mar. 1989, at 5.

24. *Id.*

25. *Id.*

of intellectual property is a significant deterrence to foreign investment.²⁶ Indonesia's economy had always relied substantially on the exports of oil and oil-related products and her dependence on foreign investment became increasingly evident after oil prices took a huge dip in the mid-1980s.²⁷ To make up for the losses incurred, the government needed to attract more foreign capital. Hence, since 1987, Indonesia has eased restrictions on foreign investors.²⁸ The government deregulated finance, reduced import barriers and altered the regulations for foreign ownership.²⁹ However, some investors who considered patent protection of paramount importance to their businesses were hesitant to invest without a patent law in the country.

At the same time, improvements on patent protection by the neighboring countries made Indonesia realize that she would be a better competitor if armed with a better set of laws. Indonesia was aware that her neighbors including Thailand, Singapore and Malaysia were keen competitors for foreign capital. Singapore established some copyright, patent and trademark laws and she continuously attracted foreign investors. If Indonesia wanted foreign investment, she must offer an improved business climate, including a more tangible form of protection for intellectual property.

Indonesia's decision to have a patent law was also partly a reaction to mounting international pressure. In mid-January 1989, Washington put trade sanctions on Thailand because the latter did not protect United States intellectual property, particularly computer software and pharmaceuticals.³⁰ The United States denied Thailand duty-free benefits on exports to the country.³¹ Indonesia could not afford to lose the duty-free benefits similar to those which Thailand lost because the United States had always been one of Indonesia's biggest foreign markets.³²

26. See Matthew Shears, *supra* note 21. Mr Nico Kansil, Director General of Copyrights, Patents and Trademarks at the Indonesian Department of Justice acknowledged that "(f)oreign investment will be promoted and transfer of technology will be encouraged by intellectual property protection." *Id.*

27. *18-Month Forecasts of International Investment Restrictions*, IBC USA LICENSING INC.; POLITICAL RISK SERVICES, July 1, 1991, (Lexis, Nexis, Omni file).

28. *Id.*

29. Lisa Errion, *Indonesia: Policies are Generating Markets for U.S. Products*, BUSINESS AMERICA, Vol. 111, No. 8, Apr. 23, 1990, at 35.

30. Bill Tarrant, *Indonesia Proposes Law to Protect Foreign Patents*, REUTERS, Jan 24, 1989.

31. *Id.*

32. Indonesia's trade with Washington is close to US\$ 5 billion a year. See Jonathan Thatcher, *Suharto, Bush Talks Seen Dominated by Economic Issues*, REUTERS, June 5, 1989.

The government finally concluded that patent laws would benefit Indonesia. In the words of Nico Kansil, the Director General of Copyrights, Patent, and Trademarks at the Indonesian Department of Justice, the protection would "induce the local Indonesian to make innovations and generate the creativity of the Indonesian people."³³ The lack of patent laws increases piracy activities which in reality hurts Indonesia. By allowing pirates to flourish, the government undercuts the legitimate companies. Furthermore, many pirates skirt taxes and various employment regulations. Ultimately, the government will be forced to deal with a host of consequences resulting from the piracy activities.

III. THE NEW PATENT LAW IN THEORY

The birth of the new patent law introduced Indonesia to a new and somewhat unfamiliar concept: the inventor or licensor of a product or process has exclusive rights to said product or process and the infringement of their rights by third parties is illegal. To better understand the workings of this patent law, it is necessary to take a detailed look at its content. It is also important to note that the patent law must be read in conjunction with Government Regulations issued subsequently. These latter documents clarify some of the broader language stated in the patent law. In this section of the comment, the laws will be laid out only to give a basic knowledge regarding the patent system that is being developed. Analyses of specific laws will follow later.

Article 1 Section 1 of the patent law defines a patent as "a special right granted by the State to an inventor for the result of his invention in the field of technology, [permitting him] to implement ["work"] his own invention by himself for a certain period or to authorize another person to implement it."³⁴ A patent would be granted "for a new invention containing an innovative aspect and applicable to industry."³⁵ To be deemed "new," the invention must not, at the time the patent application is filed, have been published in Indonesia or elsewhere, so as to enable the invention to be carried out by an expert.³⁶ An invention is innovative if it is a previously

33. Matthew Shears, *supra* note 21.

34. The text of the patent law that was available was an unofficial translation prepared by the Law Firm of Hadiputranto & Hadinoto in Jakarta, Indonesia. The text appeared in three different sections published in EAST ASIAN EXECUTIVE REPORTS, Vol. 12, No. 3, Mar. 15, 1990, at 20 (Articles 1-86); Vol. 12, No. 4, Apr. 15, 1990, at 26 (Articles 87-103) and Vol. 12, No. 5, May 15, 1990, at 25, (Articles 104-134). [Hereinafter Text]

35. Text, *supra* note 34, Article 2.

36. Text, *supra* note 34, Article 3.

unexpected matter for a person with the usual technical expertise in the particular field.³⁷

Not all inventions are deemed patentable. Article 7 explicitly cited five general instances for which a patent application would be denied.³⁸ The five unpatentable types of inventions include:

1. A production process or product contrary to public order, morality or existing laws;
2. Food and drink, including products in the form of raw material made by chemical processes for human and animal consumption;
3. New plant varieties or animal species, and any process used for the breeding of plants and animals;
4. Methods of examining, nursing, medication and surgery applied to humans and animals, but excluding the products used with these methods;
5. Theory or methodology in the field of science or mathematics.³⁹

The one special instance in which a patent may not be granted is if the President, through a Presidential Decree, suspends the patent application for up to five years.⁴⁰ The President would likely invoke this power when the government sees the need to protect and cultivate development programs in specific areas.⁴¹ This exception does not apply to existing patent holders or a patent on a priority basis that is pending at the time the Presidential Decree is issued.⁴²

The Application Process

The application procedure is specified in the new patent law. The inventor or a "subsequent recipient of the rights of the inventor" is entitled to a patent.⁴³ If the person seeking to file an application is not the inventor, a statement "with adequate supporting evidence" is needed to show that the applicant is entitled to the said invention.⁴⁴ A foreigner's application is required to go through a

37. *Text, supra* note 34, Article 2, Section 2. *See also Text, supra* note 34, Article 2, Section 3 which states that whether an invention is an unforeseen matter must be assessed "by assessing current knowledge at the time of the patent application or knowledge existing at the time of the first application submitted on a priority basis."

38. *Text, supra* note 34, Article 7.

39. *Text, supra* note 34, Article 7.

40. *Text, supra* note 34, Article 8, Section 1.

41. Duane Gingerich, *supra* note 6, at 9.

42. *Id.*

43. *Text, supra* note 34, Article 11, Section 1.

44. *Text, supra* note 34, Article 26, Section 1.

patent consultant registered at the Patent Office as a proxy of the foreigner.⁴⁵ The applicant or proxy must be legally domiciled in Indonesia.⁴⁶ The application must also contain detailed information regarding the invention in the Indonesian language.⁴⁷ The documents to be submitted as part of the application packet are: (i) a letter of application; (ii) a description of the invention;⁴⁸ (iii) one or more claims contained in the invention (a claim is "a written description on the core of the invention or certain parts of the invention which requires legal protection in the form of patent"⁴⁹); (iv) one or more pictures mentioned in the description to give explanation; and (v) an abstraction of the invention.⁵⁰ The application should also be accompanied by a fee of Rp. 200,000 (approximately 100 U.S. dollars).⁵¹

Once the Patent Office receives the application documents, they will be treated as secret documents.⁵² If any patent consultant or officer reveals the secrets on the application, he or she could face a five-year penalty.⁵³ Within six months of receiving the application, the Patent Office will publish an abstract of the invention.⁵⁴ During this time, anyone may object to the granting of the patent.⁵⁵ The Patent Office will subsequently review the objections and make a decision.⁵⁶ If there are no objections, the applicant is required to file an application for a substantive inspection.⁵⁷ This should be done after the announcement period is over, but within thirty-six

45. Text, *supra* note 34, Article 26, Section 1.

46. Text, *supra* note 34, Article 28, Section 2.

47. Text, *supra* note 34, Article 30.

48. The description must be structured as follows: title of the invention, technical field, background art, technical improvements and advantages, brief explanation of the drawing(s), mode of carrying out the invention and working example(s) and industrial applicability. See J.B. Lumenta, *Patent Act Comes into Force: Government Issues Regulations*, BNA INT'L BUS. DAILY, Oct. 31, 1991.

49. Government Regulation No. 34/1991 dated June 11, 1991 [hereinafter GR No. 34/1991], Article 1, Section 3.

50. GR No. 34/1991, Article 4. An abstraction is "a brief description regarding an invention which constitutes a resume of the main description, claim or picture." GR No. 34/1991, Article 1, Section 5.

51. Attachment to Circular of the Minister of Justice No. M.03-HC.02.10/1991 dated Aug. 22, 1991.

52. GR No. 34/1991, Article 34, Section 2.

53. A point emphasized by the Director General of Copyrights, Patents and Trademark, Nico Kansil, *RI Patent Act Takes Effect, One Request Listed*, JAKARTA POST, Aug. 2, 1991.

54. Text, *supra* note 34, Article 47, Section 2(a); Lisa Errion, *supra* note 30, at 23.

55. Text, *supra* note 34, Article 51, Section 1.

56. Text, *supra* note 34, Article 51, Section 4.

57. Text, *supra* note 34, Article 55, Section 1.

months after the receipt of the application.⁵⁸ A fee of Rp. 750,000 (approximately 380 U.S. dollars) will be charged for the inspection.⁵⁹ Within twenty-four months from the date of the request for a substantive examination, the Patent Office will render its verdict.⁶⁰ Should the patent application be approved, a Patent Certification will be issued, recorded in the General Patent Register and published in the official Patent Gazette.⁶¹ If the application is rejected, an appeal may be made to the Patent Appeal Commission which, within twelve months, will hand down a final decision.⁶²

Filing A Patent With Priority Right

The procedure for filing a patent with priority right pursuant to an international convention joined by Indonesia is slightly unclear. A priority right allows foreign work to be protected in Indonesia. The notion of priority right is stated in Article 4 Sections A(2) through I(2) of the Paris Convention.⁶³ An author can obtain protection of his or her work under the Convention in countries of the Union as well as the country of his origin.⁶⁴ Here however, the concept is a rather confusing one because, as mentioned before, Indonesia has yet to officially declare itself one of the signatories to the Paris Convention. Nevertheless, the new patent law provides for patent application with right to priority.⁶⁵ Article 29, Section 1 mandates such application be filed "within 12 months commencing from the date on which the first patent application was received by any country belonging to said convention."⁶⁶ A copy of the first letter of patent application certified by the authorized party of the country concerned must also be submitted.⁶⁷ The fact that the government has not planned out the details surrounding this area is

58. Text, *supra* note 34, Article 56, Section 1.

59. Attachment to Circular of the Minister of Justice No. M.03.HC.02.10/1991 dated Aug. 22, 1991.

60. Text, *supra* note 34, Article 61.

61. Text, *supra* note 34, Article 64, Sections 1 & 2.

62. Text, *supra* note 34, Article 71.

63. Text of the Paris Convention for the Protection of Industrial Property of March 20, 1883, as Revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at the Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1938, and at Stockholm on July 14, 1967; this was a reprint from Konrad Zweigert & Jan Köpholler, *SOURCES OF INTERNATIONAL UNIFORM LAW*, Vol. III, A.W. Sijthoff, Leiden, 1973, at 129-146.

64. *Id.*

65. The Elucidation also refers to the Paris Convention and Indonesia should be implicitly bound by the Paris Convention with respect to the patent law.

66. Text, *supra* note 34, Article 29, Section 1.

67. Text, *supra* note 34, Article 31, Section 1.

evidenced in its provision in Article 32 which states that further regulations governing this area will be stipulated at a later date.⁶⁸

Rights Of A Patent Holder

Once a patent is granted, Article 9 states that the holder is entitled to 14 years of patent protection starting from the date the patent application is filed.⁶⁹ This date and the date of expiration must be recorded in the General Register of Patents and published in the Official Patent Gazette.⁷⁰ During the 14-year period, a Patent Holder must use his patent commercially. He must "produce, sell, rent, deliver, use, to supply for sale, or rent, or deliver the patented products" or "use the patented production process to produce goods."⁷¹ The working of the patent must be carried out on Indonesian soil.⁷² When the patent expires, the holder may request a one-time only, two-year extension.⁷³ Section 1 of GR No. 34/1991 Article 63, stipulates that a written request for renewal must be submitted to the Patent Office "within a period of twelve months and at least six months before the patent expires."⁷⁴ A fee of Rp. 100,000 (approximately 50 U.S. dollars) will be charged.⁷⁵ Article 63, Section 3 promises further regulations regarding the matter.⁷⁶

Compulsory Licensing

The patent law also contains provisions for Compulsory Licensing. Article 82 allows any person to apply for the implementation of a patent after thirty-six months from the date the patent was first issued, if the said patent "had not been implemented in Indonesia by the Patent Holder even though there has been opportunity for commercial implementation of the patent which should have been utilized."⁷⁷ The applicant must show that he (1) is capable of implementing the patent himself and (2) has the facilities to fully put the patent to use.⁷⁸ Should the District Court decide that the im-

68. Text, *supra* note 34, Article 32; see also GR 34/1991 Article 45, which reads "Further regulations on the patent application with the right of priority will be stipulated by the Minister." The government is evidently uncomfortable with this area of the law.

69. Text, *supra* note 34, Article 9, Section 1.

70. Text, *supra* note 34, Article 9, Section 2.

71. Text, *supra* note 34, Article 17.

72. Text, *supra* note 34, Article 18.

73. Text, *supra* note 34, Article 42.

74. GR No. 34/1991, Article 63.

75. *Id.*

76. *Id.*

77. Text, *supra* note 34, Article 82.

78. Text, *supra* note 34, Article 83, Section 1(a).

plementation is feasible and will "yield benefits for a large part of the society," the Compulsory License will be issued.⁷⁹ The Compulsory License is valid only for the period necessary to work the patent.⁸⁰ The Compulsory License Holder shall pay the Patent Holder royalties, the amount of which will be determined by the District Court.⁸¹

Criminal Provisions

The criminal provisions begin in Chapter XII with Article 126. One who intentionally violates the rights of a patent holder by using the latter's patent for commercial gain faces an imprisonment for a maximum of seven years and a fine of a maximum of Rp. 100 million (approximately 55,000 U.S. dollars).⁸² The new law also provides for the investigation mechanism to tackle criminal acts in this field. It vests the investigative authorities not only in the State police but also in civil servants responsible for patent development. These investigators may:

1. Examine reports relating to criminal actions in the field of patent;
2. Investigate a person suspected of violation of the patent law;
3. Obtain information and evidence from individuals or entities connected with their investigations;
4. Examine all documents pertaining to their investigations;
5. Investigate locations for evidence and confiscate such evidence found;
6. Request expert assistance in the investigation.⁸³

Temporary Patent Applications Filed Under The Government Announcement of 1953

The patent law allows for the renewal of temporary patent applications filed according to the Governmental Announcement of 1953. Those who filed these temporary patent applications between August 1, 1981 and November 1, 1989 were required to submit their new applications between August 1, 1991 and July 31, 1991.⁸⁴

79. *Text, supra* note 34, Article 83, Section 1(b).

80. *Text, supra* note 34, Article 83, Section 3.

81. *Text, supra* note 34, Article 85, Sections 1 & 2.

82. *Indonesia*, E. ASIAN EXECUTIVE REP., Vol. 12, No. 5, May 15, 1990, at 20.

83. *Id.*

84. *Text, supra* note 34, Article 131, Section 1. *See also* GR No. 34/1991, Article 76.

Failure to do so would result in the expiration of those temporary patent applications.⁸⁵ If a patent is granted, the period of protection is "from the date of receipt of the patent application based on the Announcement."⁸⁶ As for patents filed more than 10 years prior to August 1, 1991, they are "deemed null and void."⁸⁷

IV. PROBLEM AREAS OF THE NEW PATENT LAW

The preceding section mentioned some of the more significant provisions of the patent law. Investors and critics alike know that the laws are not without flaws. This comment discusses problem areas in the Indonesian patent law by looking through the lenses of one of the industries affected by this new law, the pharmaceutical industry. This overview also evaluates Government Regulations No. 32/1991 and No. 34/1991 enacted on June 11, 1991 as efforts by the government to pacify the investors and clarify the laws.

The pharmaceutical industry has substantial foreign capital investments in Indonesia. These foreign pharmaceutical companies have suffered losses due to patent infringement and counterfeit medications. Yet unfortunately, several provisions of the patent law do not favor this industry. The foreign pharmaceutical companies have not been pleased with the way the Indonesian government has treated them. A 1988 drug legislation restricted foreign companies to producing drugs of their own invention. They are also required to invest in the manufacture of one of the chemical ingredients in Indonesia.⁸⁸ In addition, foreign companies are prohibited from registering generics or non-prescription over-the-counter products.⁸⁹ They have also been denied the privilege to distribute free samples to doctors since December 1987.⁹⁰ All these cut into the investors' profit margins.

This time, with regard to the patent law, the pharmaceutical industry is displeased with several things: the length of time of the patent protection; the parallel import provision; the compulsory licensing requirement; and the provision of automatic revocation for non-use. The foreign pharmaceutical companies have voiced their disagreements to the legislators. These concerns will be addressed in turn.

85. *Text, supra* note 34, Article 131, Section 2.

86. *Text, supra* note 34, Article 131, Section 4.

87. *Text, supra* note 34, Article 131, Section 3.

88. *Id.*

89. *Id.*

90. *Id.*

Period Of Protection

The fourteen-year duration of the patent, starting from the date of application, is deemed too short.⁹¹ The development and testing of the drugs takes between eight and twelve years. The time for patent examination, and occasionally appeal, all translate to granting different inventions different protection terms. Furthermore, the government only has about 30 patent examiners.⁹² It could take quite some time before a new patent application gets processed.⁹³ If the applicant needs to appeal the Patent Office's initial decision and later obtains a favorable verdict from the Patent Appeal Commission, an additional year may have elapsed. This would in essence grant patent owners substantially less than fourteen years of protection.

To settle this concern, one of two options, or a combination of both could be done. The first option is to employ more patent examiners to expedite the registration and inspection processes. The Indonesian government should have the foresight to see that additional examiners will be necessary. Now is the time to train its examiners so that they will be ready to meet the demands in the future. The other option is to change the law so that the patent protection period accrues upon the granting of the patent application. This measure would be fair to all industries. A combination of the two would certainly appease numerous companies and potential investors.

Parallel Import

The pharmaceutical industry is also opposed to Article 21. Article 21 states that "(t)he importation of patented products or products made by patented production process or equivalents produced by anyone other than the Patent Holder shall not constitute a violation of the patent concerned except in certain cases to be further regulated by Government Regulation."⁹⁴ This provision threatens the pharmaceutical companies in Indonesia because it allows imports to enter the market and compete directly with their products. Article 21 can potentially render a patent protection valueless.

However, it is necessary to look at the Indonesian govern-

91. *Indonesia Agrees on Patent Protection*, PHARMACEUTICAL BUS. NEWS, Nov. 24, 1989.

92. *Enforcement Rules Needed for Patent Act*, JAKARTA POST, Apr. 7, 1991, at 1. There may be more patent examiners now.

93. *Id.*; see also *Indonesia*, BUSINESS ASIA, Aug. 5, 1991, at 274.

94. *Text, supra* note 34, Article 21. "Equivalents" probably means "counterfeits."

ment's concern to fully comprehend the controversy. By enacting the 1988 drug legislation for example, the government was able to promote domestic industries. The manufacturing of one chemical per company cumulated into numerous factories, which simultaneously translated into jobs and the transfer of valuable know-how. Indonesia is anxious to learn skills and formulae. The fact that the government must protect this interest, which poses a formidable barrier to foreign investment, forces the government to walk on a fine line. A disequilibrium towards either side will be costly to both parties.

GR 32/1991, the promised regulation mentioned in the Article 21, is proof of how the government treads the line with caution and compromises. Article 1 of GR 32/1991 attempts to pacify the pharmaceutical industry by allowing the companies to import certain listed products without a violation.⁹⁵ The Attachment names fifty pharmaceutical products. Although the list is subject to changes made by the government, the products are essential to many pharmaceutical companies. The government also added the clause "used for the protection of medicines in Indonesia" to emphasize its willingness to cater to the demands of the pharmaceutical industry.⁹⁶

Compulsory Licensing

One other burdensome provision deals with compulsory licensing. As mentioned before, anyone may apply for a compulsory license thirty-six months after a patent has been granted. If the Patent Holder can convince the Court that the non-use is due to some impossibility, for example the pending of a certain health regulation, the Court can adjourn or dismiss the case.⁹⁷ The foreign pharmaceutical industry argues that this provision hampers creativity and innovation. Compulsory licensing should be a last resort, a mechanism to be used only if affable license negotiation with a patentee becomes difficult. In all fairness to Indonesia, such a regula-

95. Government Regulation No. 32/1991 dated June 11, 1991 [hereinafter GR No. 32/1991], Article 1 reads:

(e)xcept raw materials or certain products as mentioned by the Attachment of this Government Decree, the import of patented products or products manufactured through a process under patent which is carried out by other people holding the patent and used for the production of medicines in Indonesia, is a violation of the patent rights.

96. *Id.* See also *Importation of Patented Drugs Restricted*, JAKARTA POST, Sat. June 15, 1991.

97. *Text, supra* note 34, Article 84.

tion is not unreasonable, given the government's agenda to boost the local pharmaceutical companies.

Automatic Revocation

Article 94 is another provision deemed hostile by the foreign pharmaceutical companies. The Article pertains to the revocation of patents. Failure of a patentee to use his patent in Indonesian territory within forty-eight months from the date it was granted will result in the invalidation of said patent.⁹⁸ The foreign pharmaceutical companies argued that 4 years is a very small window of time for them. It is quite impossible for a company to start marketing a new product or establish a local production within this time frame. Furthermore, this provision contradicts Article 5(A)(3) of the Paris Convention (London Text). The Paris Convention article states that a revocation may occur only when the prior grant of a compulsory license has been found inadequate to prevent the abuse of rights. Articles 65 and 66 of GR 34/1991 eliminated the harshness of the automatic revocation provision. Article 65 made the non-use clause inapplicable "if the invention is not implemented or used in Indonesia in connection with the failure to get a license to make or market the product resulted with the said patent in Indonesia."⁹⁹ Article 66 couches the government's favoritism for the local pharmaceutical industry by indicating in Section 1 that the use of "certain" patents outside Indonesian territory would be deemed to be use within Indonesian territory insofar as "the product resulting from the patent is marketed in Indonesia and in the neighboring countries. . . ."¹⁰⁰ Section 2 defines "certain" patents as those which are given the privilege by the Minister based on substantial reasons.¹⁰¹

These regulations allow both the foreign investors as well as the government to come out as winners. The foreign investors enjoy some exceptions given to them, while the government keeps its control by letting a Minister grant the privilege. However, such compromises may raise a host of additional concerns from industries which believe they are not as protected as the pharmaceutical industry. A little discrimination might be tolerated at the outset, but it cannot continue. The laws in place should be well-drafted, with few or no regulations to amend and in essence "weaken" the

98. *Text, supra* note 34, Article 94.

99. GR No. 34/1991, Article 65.

100. *Id.* at Article 66.

101. *Id.*

effects. It would be unfortunate should the original rule become the exception.

While the above-mentioned concerns are those related to the pharmaceutical industry, they are shared by numerous other industries. The pharmaceutical companies continue to lobby for changes to be announced in future Government Regulations in particular as to health regulations which have an impact on patents. Only time will tell if their efforts are rewarded.

V. GOVERNMENT MEASURES TO FACILITATE THE IMPLEMENTATION OF THE PATENT LAW

The biggest barrier to the success of protecting intellectual property through the patent laws lies not within the laws but in their enforcement. Without the necessary mechanisms to ensure compliance with the law, this patent system can be rendered ineffective. The government is not oblivious to this fact. Hence, it has undertaken several measures to prepare for the implementation stage.

First, the government knows that high quality patent consultants make a big difference to the system. A knowledgeable patent consultant can give a comprehensive explanation of the system to potential patent applicants. A better prepared patent application helps accelerate the application process. Hence, in Government Regulation No. 33/1991 dated June 11, 1991, President Suharto stipulated a Special Registration for Patent Consultants. The Elucidation of GR 33/1991 states that "(a)mong others the Law emphasizes that patent applications by the inventor or the one entitled to it who is domiciled outside the territory of the Republic of Indonesia must be submitted through Patent Consultants."¹⁰² Although the patent law itself only required applications filed as proxy to be handled by a Patent Consultant, the Elucidation is the better authority. To qualify as a Patent Consultant, a person must hold a certificate as a "Graduate of Technology and Natural Science or another field" and must possess, as of November 1, 1991, two years of experience as a Patent Consultant handling patent applications for governmental or private interests. Such qualified persons may register within six months of the enactment date of GR 33/1991.¹⁰³ The government is quick to explain that such registration is a temporary

102. Elucidation of Government Decree No. 33/1991 on Special Registration for Patent Consultants, June 11, 1991.

103. A clarification of Article 2 of the Elucidation GR No. 33/1991 on Special Registration for Patent Consultants, June 11, 1991.

one. It is special because "it is not fully based on the conditions as usually determined for Patent Consultants."¹⁰⁴ This measure is merely to get the process moving. After the cut-off date, the government will impose more stringent requirements for qualifications as patent consultants.¹⁰⁵

The government is also giving its laws some bite by adequately training its police force. When Indonesia sought to improve its copyright protection by making frequent raids, its efforts were crippled by the fact that the police lacked the "technical skills" required to identify illegal goods.¹⁰⁶ Patent infringement is even more elusive. The government has asked the cooperation of the patent holders to put out manuals to educate police and help them combat the sale or distribution of illegal goods.¹⁰⁷

Yet another means relied on at this early stage of implementation is to allow patent holders who have discovered the infringement of their patents to easily obtain preliminary injunctions. They can seek this temporary remedy before they try for a more substantial prosecution of the violation. Such a measure prohibits the violators from continuous infringement while awaiting trial. Article 123 is the embodiment of this principle. A "(j)udge may order said patent violation to be stopped. . . while the claim is being investigated by the District Court."¹⁰⁸

The government is also educating the people about intellectual property rights. Prominent speakers from all over the world have been flown in to "spread the word."¹⁰⁹ The newspapers have been printing articles explaining in layman's terms the essence of the patent law. The protection of intellectual property is a new concept to a nation that has had free access to information regarding manufacturing, processing, etc. Knowledge about the patent laws, their objectives and the economic consequences of the violation of these laws will give the Indonesian public a better awareness of the significance of patents in their society.

104. A clarification of Article 3 of the Elucidation GR No. 33/1991 on Special Registration for Patent Consultants, June 11, 1991.

105. P.D.D. Darmawan, *Patent Implementing Regulations*, IP ASIA, July 4, 1991, at 10.

106. *Indonesia; Fulfilling the Promise*, INSTITUTIONAL INVESTOR, Apr. 1991, at S19.

107. *Id.*

108. *Text, supra* note 34, Article 123, Section 2; *Indonesia, supra* note 81, at 25.

109. *To Enforce Patent Act, Ministry of Justice Will Issue Six Decrees*, JAKARTA POST, Aug. 1, 1991.

VI. TWO SUGGESTIONS FOR THE INDONESIAN GOVERNMENT TO MAKE THE PATENT LAW MORE EFFECTIVE

The government has shown signs that it is serious in its endeavor to reduce, if not eliminate, qualms about poor intellectual property protection. However, though the government is taking measures to ensure the smooth implementation and effectiveness of the patent law, there are two other means which may be worth considering: 1) tie the idea of intellectual property protection more closely to the ideals of the Pancasila; and 2) introduce *ex parte* injunctions similar to Anton Pillar orders and/or Mareva injunctions in common law countries.

1. The Teachings of the Pancasila

The Pancasila is the five principles of the state ideology of Indonesia. The principles are: (1) Belief in God; (2) Just and civilized humanity, including tolerance, to all people; (3) Unity in Indonesia; (4) Democracy led by the wisdom of deliberation among representatives of the people; and (5) Social justice for all. In a speech on October 2, 1990, the Minister of Justice, Dr Ismail Saleh stated in passing that the protection of intellectual property through patents should become clear to Indonesians because the teachings of the Pancasila prompt people to respect the property of others.¹¹⁰ This statement, with reference to patents, translates to the virtues of respecting the rights of inventors or patent holders to their patented inventions, as well as the rights of license holders who paid royalties to their licensors.¹¹¹ Dr. Saleh's comment deserves a little more thought. The Pancasila underlies Indonesian life; an association of a new concept with part of a national philosophy is a simple but effective means to bring home the point of the patent laws to the Indonesian public.

2. The Use of *Ex parte* Injunctions

An Anton Pillar order, named after a well-known English case *Anton Pillar KG v. Manufacturing Processes Ltd.* (1976 Ch. 55), is an interlocutory order which a plaintiff can seek to allow him or her to enter a defendant's premises and seize any documents or other

110. "Sambutan Menteri Kehakiman Republik Indonesia Pada Loka Karya Keliling Di Bidang Paten Bagi Para Aparat Penegak Hukum" address by the Minister of Justice, Dr. Ismail Saleh, Jakarta, Oct. 2-3, 1990.

111. *Id.*

evidence of patent or copyright infringement.¹¹² The order is made ex parte and the defendant often has no notice of the upcoming search and seizure.¹¹³ This is an effective means to discover the suppliers and/or buyers of the illegally manufactured products.¹¹⁴ Since there is a great potential for abuse, courts are generally cautious and hesitant to give Anton Pillar orders.¹¹⁵ The plaintiff is required to show: 1) a very strong prima facie case; 2) potential of serious damages; 3) clear evidence of defendant possessing some incriminating assets or documents; and 4) a potential that the defendant may destroy the incriminating evidence before a case can be brought against him.¹¹⁶

Hong Kong boasts of the best seizure and impoundment record in the world since its courts started granting Anton Pillar orders more liberally.¹¹⁷ The Indonesian government may be well-advised to consider using the same tool to combat copyright infringements and simultaneously enhancing its patent protection.

Another development by the courts as a response to fighting piracy is the Mareva injunction.¹¹⁸ This is a powerful instrument that freezes the defendant's assets and allows only for the disposal of limited expenses until the case comes to the court.¹¹⁹ The defendant is thus prevented from moving his or her assets out of the country and the plaintiff can get adequate compensation if the case is ruled in his favor.

Sometimes the threat of being sued and losing in court is powerful enough to deter patent and/or copyright infringements. The Indonesian patent law may be more effective when aided by the mere presence of the Anton Pillar order and the Mareva injunction. It is not difficult for the Indonesian courts to look into these remedies and incorporate them in their current legal system.

The government has set out to do an immense task: to educate the public about intellectual property protection and to alert them to the moral wrongfulness of piracy. It may be advisable for the

112. Justinian, *Copyright and Power Over Pirates*, THE FINANCIAL TIMES LTD., Sept. 20, 1982, Section 1, at 12.

113. *Id.*

114. *Id.*

115. *Computer Piracy in Hong Kong: The Golden Arcade, Part I*, IP ASIA, Aug. 15, 1988, at 3.

116. *Id.*

117. *Enforcement News, Asia USITC Report: How Did Asia Score?*, IP ASIA, Apr. 22, 1988, at 30.

118. See Justinian, *supra* note 111, at 12.

119. *Id.*

government to establish milestones at various intervals to monitor the situation. The public response to new laws and regulations should be tracked so as to enable the government to quickly identify and remedy problems which may arise.

VII. WILL THIS NEW PATENT LAW BE SUCCESSFUL?

The implementation of the patent laws will be the key to the success of this system. Nonetheless, the answer to the question "Will this new patent law be successful?" depends also on what is deemed a success. If the increase in foreign investments is the chosen yardstick, the patent law may not be "successful" during the first two or three years. Foreign investors may choose to wait to see how the government will implement the laws they have written to evaluate the extent of the protection in theory as well as in practice. While it may be impossible to ascertain the number of new foreign or indeed local investments attributable to the existence of the patent law alone, it is safe to say that the patent law will arrest the amount of apprehension of investing in Indonesia.

The patent law will also persuade current businesses in Indonesia that the government is doing its best to protect their products. Investors may decide to give the patent law some time and the government some cooperation by assisting with the education of the public regarding intellectual property rights.

If the yardstick used to measure the success of the patent law is the reduction of piracy activities, it would be almost impossible to speculate on the effectiveness of the law. Unfortunately, the economic rewards of piracy are more immediate and much easier to define than those of protecting intellectual property rights. It will be difficult to convince consumers to cease buying pirated products. So long as the demand is high, pirates will take their chances.

VIII. CONCLUSION

There has been much discussion about Indonesia's new patent laws. Some potential foreign investors are slightly apprehensive; others are optimistic. Some current investors are suspicious or nonchalant; yet others are merely curious. No matter how one looks at this development, it is apparent that the Indonesian government is taking a significant step in the right direction. It is time that Indonesia demolish her unsightly image as one of the world's worst intellectual property protectors. However, we should not expect the problem to disappear immediately. It will take time before Indonesia becomes comparable to the United States or the European Com-

munity in the area of intellectual property protection. Nonetheless, the government should be commended for its efforts. With the help of the Indonesian people and foreign investors alike, the problem of pirating or copying foreign goods will eventually be contained.

THE POLYMERASE CHAIN REACTION (PCR): THE SECOND GENERATION OF DNA ANALYSIS METHODS TAKES THE STAND

Kamrin T. MacKnight†

TABLE OF CONTENTS

INTRODUCTION	288
BASIC GENETICS AND DNA REPLICATION.....	289
FORENSIC DNA ANALYSIS	292
<i>Direct Sequencing</i>	293
<i>Restriction Fragment Length Polymorphism (RFLP)</i>	294
Introduction	294
Technology	296
<i>Polymerase Chain Reaction (PCR)</i>	300
History	300
Technology	304
The Human Leukocyte Antigen System (HLA)	308
Population Genetics and the DQ α Level of Discrimination.....	311
Perceived Problems Associated with PCR.....	314
"Allelic Drop Out"	314
Sensitivity and Contamination.....	315
<i>Contaminating DNA from Species Other Than Humans</i>	316
<i>Contaminating DNA from "Extraneous" Humans</i> ..	317
Small Number of Forensic Laboratories Using the Test	319
Interpretation Problems	320
<i>Sexual Assault Evidence Samples</i>	320
<i>Other Sample Types</i>	321
Laboratory Design and Test Protocols	322
ADMISSIBILITY AND OTHER ISSUES INVOLVING DNA ANALYSIS IN CRIMINAL TRIALS	325

Copyright © 1993 by Kamrin T. MacKnight.

† B.S. Brigham Young University; M.A. San Jose State University; Ph.D. University of California, Berkeley; Candidate, J.D. 1993 Santa Clara University School of Law, Santa Clara. Dr. MacKnight is a technical consultant in the law firm of Haverstock, Medlen & Carroll, San Francisco, CA.

<i>California's Kelly-Frye Test</i>	327
<i>The Bar's Response to DNA Testing</i>	331
<i>Expert Witnesses</i>	333
<i>The Impact of People v. Castro</i>	338
PROPOSED REGULATIONS	340
<i>History</i>	340
<i>Validation Studies, Standards and Proficiency Testing</i>	343
<i>AmpliType[™] Kit Development</i>	344
<i>California Association of Crime Laboratory Directors</i> <i>(CACLD) Tests</i>	345
<i>Federal Legislation</i>	348
<i>State Regulation</i>	349
<i>Self-Regulation</i>	350
<i>Who Will Be Regulated and By Whom</i>	351
CONCLUSIONS AND PROGNOSTICATIONS FOR THE FUTURE .	352

INTRODUCTION

The goal of this Comment is to discuss and describe for the non-scientist attorney: (1) the technologies involved in the three major methods of DNA testing; (2) potential uses for the polymerase chain reaction (PCR), and issues surrounding its use in the forensic setting, including the cases to date; and (3) proposed regulations and legislative action. Also, this comment refutes some of the criticisms levelled against DNA testing in general and attempts to correct some of the errors in previously published legal papers regarding DNA technology and cases. Prosecutors, commercial laboratories, and the media are not the only ones who are pushing DNA profiling evidence into court. It is hoped that the "stunned defense bar"¹ will realize the tremendous exculpatory potential of DNA analysis.

While the technique utilizing restriction fragment length polymorphisms (RFLP) has been accepted by many more appellate level and higher courts,² PCR has also been accepted by some ap-

1. Janet C. Hoeffel, Note, *The Dark Side of DNA Profiling: Unreliable Scientific Evidence Meets the Criminal Defendant*, 42 STAN. L. REV. 465 (1990); Rorie Sherman, *DNA Unraveling*, 15 NAT'L L.J. 1 (1993).

2. United States v. Jakobetz, 955 F.2d 786 (2d Cir. 1992); People v. Axell, 81 Cal. Rptr. 2d 411 (Cal. Ct. App. 1991); State v. Pennington, 393 S.E.2d 847 (N.C. 1990); Kelly v. State, 792 S.W.2d 579 (Tex. Ct. App. 1990); Glover v. State, 787 S.W.2d 544 (Tex. Ct. App. 1990); State v. Woodall, 385 S.E.2d 253 (W. Va. 1989); Caldwell v. State, 393 S.E.2d 436 (Ga. 1990); People v. Wesley, 533 N.Y.S.2d 643 (N.Y. Co.Ct. 1988); Martinez v. State, 549 So.2d 694 (Fla. Dist. Ct. App. 1989); State v. Pennell, 584 A.2d 513 (Del. Super. Ct. 1989) [DNA test results admitted, but not probability evidence]; Cobey v. State, 559 A.2d 391 (Md. Ct. Spec. App. 1989); Andrews v. State, 533 So.2d 841 (Fla. Dist. Ct. App. 1988).

pellate courts³ and by the Virginia Supreme Court.⁴ However, as recently demonstrated by the California First District Court of Appeal,⁵ acceptance of RFLP is not uniform. Given the overwhelming acceptance and adoption of PCR in the scientific community, it is likely that such acceptance by the judicial system will come with time.⁶

Probably because of the quantity of attention given RFLP, commonly referred to as "DNA Fingerprinting," it is a little known or appreciated fact that PCR was successfully used to the benefit of the defense in the very first criminal case involving DNA analysis in the country.⁷ However, PCR is useful for both the prosecution and defense, as was shown in a recent San Mateo County, California case.⁸ This case dramatically illustrated the usefulness of PCR in both exonerating and implicating suspects of such crimes as sexual assault.

BASIC GENETICS AND DNA REPLICATION

In recognition of the fact that many attorneys do not have easy access to genetics texts⁹ recent enough to describe PCR, and the

3. Fuller v. Texas, 827 S.W.2d 919 (Tex. Crim. App. 1992); Trimboli v. Texas, 817 S.W.2d 785 (Tex. Ct. App. 1991).

4. Spencer v. Commonwealth, 393 S.E.2d 609 (Va. 1990); Spencer v. Commonwealth, 385 S.E.2d 850 (Va. 1989); Spencer v. Commonwealth, 384 S.E.2d 775 (Va. 1989); Spencer v. Commonwealth, 384 S.E.2d 785 (Va. 1989).

In another case, the Massachusetts Supreme Court agreed with an indigent defendant that PCR might help exonerate him, but refused to require the state to fund post-conviction investigations that might reveal exculpatory evidence. Commonwealth v. Davis, 574 N.E.2d 1007 (Mass. 1991).

5. People v. Barney, 10 Cal. Rptr.2d 731 (Cal. Ct. App. 1992).

6. The wide and enthusiastic support and acceptance of PCR in the scientific community is illustrated by the inclusion of over 12,000 PCR references in the Medline database accessed through LEXIS. A LEXIS (MEDIS, MEDLINE Library, 86-91 File) search ("polymerase w/1 chain w/1 reaction") conducted on 14 Jan. 1993 retrieved 12,016 references. A narrower, modified search ("and forens!") retrieved 94 references.

7. Pennsylvania v. Pestinakis, cited in *DNA Typing Draws First Blood in Pennsylvania*, SCI. SLEUTHING NEWSL., Summer 1987, at 1, 1.

8. People v. Quintanilla, No. C-23691 (San Mateo Super. Ct., Aug. 16, 1991). In this case, the DNA typing requested by the initial suspect excluded him. Based on this and other evidence, the prosecution dismissed the charges against the suspect. Approximately one year later, a second suspect, already under investigation in several rape cases, was implicated. This suspect was included through PCR typing. Although various samples had been submitted to Cellmark Diagnostics (Germantown, MD) for RFLP analysis, Cellmark was unable to obtain banding patterns. Nonetheless, PCR results implicated him, he matched the original victim's physical description, his wife possessed jewelry stolen from the victim, and his fingerprints matched those lifted from her car. Following a *Kelly-Frye* hearing, the PCR evidence was admitted in his trial, and he was convicted. *Id.*

9. For exhaustive coverage of genetics, the reader is referred to such texts as BENJAMIN LEWIN, *GENES* (2d ed. 1985); BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE*

observation that accurate and sufficiently simple (yet detailed enough to be useful) descriptions of DNA technology are few and far between in the legal literature, a relatively large portion of this comment is devoted to the science involved in DNA analysis.

Deoxyribonucleic acid (DNA) is the "genetic blueprint" or "code" which makes each living organism, with the exception of identical twins, unique from all others. DNA is contained within every nucleated cell in the human body.¹⁰ With the exception of the reproductive cells, human DNA is arranged in 23 pairs of distinct and separate chromosomes.¹¹ Each chromosome is composed of many "genes"¹² and the entire DNA complement is called the "genome."¹³ Thus, the human genome is composed of 46 total chromosomes which are paired such that homologous chromosomes are bound together within the nucleus.

Chromosomes are divided into two general groups—the autosomes and sex (X and Y) chromosomes. Autosomes are all chromosomes other than the sex chromosomes. Somatic human cells (body cells that are non-reproductive) have 22 pairs of autosomes and 1 pair of sex chromosomes. The total number of paired chromosomes in somatic cells is called "diploid" (2n). Reproductive cells (egg and sperm) are called "gametes" or "germ cells." Gametes contain the "haploid" chromosome number (n). This means

CELL (1983); MAXINE SINGER & PAUL BERG, GENES AND GENOMES (1991), and virtually any recent biology or molecular biology textbook.

10. The major portion of DNA in each cell is located within a "nucleus." Thus, cells without nuclei do not contain DNA. While most cells are nucleated, such cells as the mature red blood cells of mammals do not have nuclei and thus do not contain DNA. See LUIS C. JUNQUEIRA & JOSE CARNEIRO, BASIC HISTOLOGY 261 (4th ed. 1983).

Animals and plants also contain a minor amount of extrachromosomal DNA. This DNA is contained within organelles responsible for energy production. Thus, in animal cells this DNA is located within mitochondria; in plants, it is located within chloroplasts.

11. Humans have 22 matched pairs of autosomes and one pair of sex chromosomes. LORNE T. KIRBY, DNA FINGERPRINTING 8 (1990).

12. Although the term "gene" was coined by Johanssen in the early 1900's, Gregor Mendel advanced the concept of the "gene" as early as 1865. *Id.* at 7.

13. The human genome is composed of approximately 3 billion base pairs. Chromosomes range in size from about 80 to 300 million base pairs. It has been estimated that only a minor fraction of DNA (perhaps less than 10%) represents coding DNA and regulatory sequences. The remainder consists of repetitive and other sequences, the function and importance of which are not presently understood. Eric D. Green & Robert H. Waterston, *The Human Genome Project; Prospects and Implications for Clinical Medicine*, 266 JAMA 1966, 1967 (1991).

Of the estimated 50,000 to 100,000 genes present in the human genome, approximately 5000 have been catalogued, 1900 have been assigned to particular chromosomes and 600 have been isolated (in cloned form). Less than 0.1% of the DNA sequences in the human genome have been determined. *Id.*

that they contain one copy of each autosome and one sex chromosome.

Basically, one chromosome in each pair is inherited from the individual's mother, and the other chromosome is inherited from the father. Thus, during normal embryonic development, a particular gene from the father will be paired with the homologous gene from the mother.¹⁴ Each homologous chromosome pair contains genes situated in pairs at certain places ("loci"). Paired genes which code for certain characteristics are called "alleles."¹⁵

As organisms must be able to replenish dead cells as well as produce gametes, DNA replication is an important facet of cell growth and development. Each time somatic cells divide,¹⁶ DNA replication must occur in order to ensure that each of the two daughter cells will contain a diploid chromosomal number.¹⁷ In the first step of this complicated process, the rungs of the "ladder" are separated between the paired bases to produce two "complementary" strands of DNA.¹⁸ Each strand becomes a "template" to

14. This is made possible by the process known as "meiosis," which occurs during the development of eggs and sperm (gametes). LEWIN, *supra* note 9, at 688. In the process of meiosis, after chromosomal replication occurs, the nucleus and cell divide twice to produce four cells, each with one-half the original chromosome number. Thus, each gamete will contain only one of the two homologues of the parent chromosomes (it is "haploid"). Somatic cells contain two copies of each chromosome and are called "diploid." *Id.* at 27-33.

15. Alleles are alternate forms of the genes that determine the expression of some particular characteristic. KIRBY, *supra* note 11, at 7-8.

While a person may inherit the allele for blue eyes from one parent and the allele for brown eyes from the other, only one eye color is normally expressed. In this example, the brown eye gene is "dominant" and the blue eye gene is "recessive;" this brown-eyed person would be "heterozygous" for the eye color gene. If the person had inherited brown eye genes from both parents, he would be "homozygous" for the gene which codes for eye color. *Id.* at 8.

16. The process whereby a somatic cell divides after chromosomal replication is called "mitosis." LEWIN, *supra* note 9, at 688.

17. For example, when skin is injured, new skin cells must be produced in order to replace the dead ones. The skin cells surrounding the damaged area are stimulated to begin dividing. The DNA of these cells is replicated and the cells undergo "mitosis," or cell division. This ensures that normal skin cells containing the proper diploid number of chromosomes will replace those killed as a result of the injury.

18. DNA is commonly described as a "twisted helix," "twisted ladder," or "spiral staircase." The ladder rungs (or steps in the staircase) are composed of pairs of "nucleotide" bases. Within DNA, there are four bases—adenine (A), thymine (T), cytosine (C) and guanine (G). Normally, each base is paired with another through hydrogen bonds, with adenine paired with thymine and cytosine paired with guanine. The ladder's handrails are composed of sugar (deoxyribose) and phosphate molecules. Strictly speaking, a nucleotide is a base connected to a sugar and a phosphate. The paired bases are often referred to as "base pairs." It is the particular base sequence which determines the characteristics of the individual animal.

The other nucleic acid, ribonucleic acid or "RNA," is composed of the same nucleotides, with the exception that thymine is replaced by uracil (U) (which like thymine, pairs with

which new nucleotides are added. To accomplish this, an enzyme called "DNA polymerase" travels along each of these separated "template" strands, binding complementary bases in their appropriate places thereby building new ladders from each of the two strands and producing two identical DNA molecules from one original parent DNA. This process allows each daughter cell to contain one DNA strand from the parent cell and maintains the genetic integrity of the organism.

Although DNA polymerase is not entirely mistake-proof, it is quite reliable and will faithfully reproduce the parent DNA molecule. As DNA replication is a very important function in cell division, DNA polymerases are not limited to complex animals.¹⁹ While there are many other enzymes involved in DNA replication,²⁰ DNA polymerase is the enzyme of primary interest in the polymerase chain reaction.

FORENSIC DNA ANALYSIS

The genes of greatest interest in genetic analysis are those for which there are many variations and are thus termed "polymorphic."²¹ Usually, for a locus to be considered polymorphic, the most common allele must occur at a frequency of less than 99% and according to the Hardy-Weinberg law,²² at least 2% of the population must be heterozygous at that locus.²³ At the molecular level, polymorphism may result from a single nucleotide base change, or from a change in the number of tandem repeats in a

adenine). RNA is copied from the DNA and is involved in protein production. Some viruses (e.g., the retroviruses, such as the human immunodeficiency viruses, and feline leukemia virus) have RNA as their genetic material instead of DNA.

19. Lower organisms such as bacteria, fungi and parasites have their own DNA polymerases which carry out the same replication functions. As discussed below, DNA polymerases and other enzymes from bacteria and other organisms are useful tools in molecular biology and genetic engineering.

20. For descriptions of the structures and functions of the various enzymes involved in eukaryotic (e.g., human) and prokaryotic (e.g., bacteria) DNA replication, see the appropriate chapters in ARTHUR KORNBERG, *DNA REPLICATION* (1980).

21. "Polymorphism" refers to different forms of the same basic structure. There are many examples of polymorphism in human genetics, such as ABO blood types and eye color.

22. According to the Hardy-Weinberg law, in a large randomly mating population, where no disturbances by outside influences such as mutation, migration, or selection exist, the relative proportions of the different genotypes remain constant between generations. KIRBY, *supra* note 11, at 168. See also Victor Weedn, *DNA Profiling*, 1 EXPERT EVIDENCE REP. 61, 66 (1989), for a simple explanation of the Hardy-Weinberg principles.

The "genotype" is the genetic make-up of an organism. The "phenotype" is the appearance or other characteristic of the organism which results from the interaction of its genetic constitution with the environment. LEWIN, *supra* note 9, at 25, 689.

23. KIRBY, *supra* note 11, at 25.

repetitive DNA sequence. The changes may be neutral, with no detectable phenotypic effect, or they may result in the production of different forms of the same protein or enzyme ("isozymes")²⁴ or they may be lethal.

There are three basic DNA analysis methods commonly used to determine identity and relatedness between individuals: (1) direct gene sequencing or "mapping," (2) RFLP, and (3) PCR. Prior to testing by any of these methods, electrophoresis or spectrophotometry is often used to determine the amount and size characteristics of the DNA present in the sample, if any.

Direct Sequencing

The goal of direct sequencing is to determine the exact nucleotide sequence present in the DNA molecule of interest.²⁵ Because DNA is ultimately responsible for the uniqueness of each individual, direct DNA sequencing is the only method which can determine identity with 100% accuracy.²⁶

Understandably, mapping the large numbers of genes present on each individual chromosome by direct sequencing requires Herculean efforts.²⁷ Nonetheless, due to advances in equipment and

24. *Id.*

25. ALBERTS ET AL., *supra* note 9, at 185.

26. George Sensabaugh, *Use of DNA Fingerprinting in Forensics*, Paper presented at the American Society for Microbiology, Northern California Branch and Northern California Association of Public Health Microbiologists, 8th Annual Combined Fall Conference (October, 1991).

27. Sequencing the human genome is the goal of the "Human Genome Project," an ambitious, international, 15-year (minimum) cooperative venture. Anthony V. Carrano, *Human Genome Project—A Global and Local Perspective*, Paper presented at the American Society for Northern California Branch and Northern California Association of Public Health Microbiologists, 9th Annual Combined Fall Conference (Oct. 1992). PCR is largely responsible for making a project of this magnitude feasible. As stated previously, in order to analyze each genomic sequence, many copies of DNA are necessary. Thus, the researchers must make thousands, if not millions, of copies of each gene. This would take much longer if traditional methods of molecular cloning such as those described in R.W. OLD & S.B. PRIMROSE, *PRINCIPLES OF GENE MANIPULATION* (4th ed. 1989) and J. SAMBROOK ET AL., *MOLECULAR CLONING* (2d ed. 1989) were necessary.

The implications of sequencing the human genome are staggering. The recent discoveries of the genes associated with muscular dystrophy, manic depression, cystic fibrosis, and Alzheimer's disease are merely illustrative aspects of the tremendous potential presented by this project. Hereditary defects may also be diagnosed more efficiently and earlier in pregnancies. Eventually, such defects may be eliminated through sophisticated genetic techniques. See Green & Waterston, *supra* note 13.

Concerns have arisen in association with the Human Genome Project, including privacy issues related to the database which will be generated. See Deborah Jackson, *Hacking the Genome*, SCI. AM., Apr. 1992, 128, 128, for a description of the problems involved in establishing the database. Other issues include patenting of the DNA involved in this project. While some scientists within the National Institutes of Health desire to patent DNA of un-

knowledge, the combination of either direct sequencing or RFLP and PCR will probably become the third generation of DNA testing.²⁸

Restriction Fragment Length Polymorphism (RFLP)

A. Introduction

RFLP is the DNA testing technique commonly referred to within the legal profession as "DNA fingerprinting," due to the barcode-like results observed in the ultimate product of the analysis.²⁹ RFLP, the first generation in DNA analysis for casework, was developed by Alec Jeffreys and his colleagues in Britain.³⁰ It has been used extensively in the United States, the United Kingdom,³¹ Canada³² and China.³³ RFLP was used in the first sensa-

known coding specificities, many others are opposed to patenting these gene sequences. In fact, this controversy over patenting contributed to the resignation of James Watson as the head of the Human Genome Project. See Leslie Roberts, *Two Strikes Against CDNA Patents*, 257 SCI. 1620 (1992).

28. See Carolyn S. Harrington et al., *HLA DQA Typing of Forensic Specimens by Amplification Restriction Fragment Length Polymorphism (RFLP) Analysis*, 51 FORENSIC SCI. INT'L 147 (1991); Kentaro Kasai et al., *Amplification of a Variable Number of Tandem Repeats (VNTR) Locus (pMCT118) by the Polymerase Chain Reaction (PCR) and Its Application to Forensic Science*, 35 J. FORENSIC SCI. 1196 (1990); Ulf B. Gyllensten & Henry A. Erlich, *Generation of Single-Stranded DNA by the Polymerase Chain Reaction and its Application to Direct Sequencing of the HLA-DQA Locus*, 85 PROC. NAT'L ACAD. SCI. 7652 (1988).

29. Because DNA typing is based on very different principles than traditional fingerprinting, it is somewhat unfortunate that the term "Fingerprinting" has been associated with DNA testing. While this term has traditionally only referred to RFLP, some commentators unfamiliar with the science and technology group all DNA testing methods, including PCR applied to specific genetic loci within the term. Also, contrary to some accounts, "DNA Fingerprinting" was not "discovered" by Jeffreys, it was invented by him. See Ricardo Fontg, Comment, *DNA Fingerprinting: A Guide to Admissibility and Use*, 57 MO. L. REV. 501, 502-503 (1992).

30. Jeffreys' work developed from fundamental research done by E.M. Southern on the technique of "Southern blotting" DNA from electrophoresis gels onto membranes (E.M. Southern, *Detection of Specific Sequences Among DNA Fragments Separated by Gel Electrophoresis*, 98 J. MOLECULAR BIOLOGY 503 (1975)) and the work of Wyman and White on a polymorphic DNA locus which was characterized by a number of "variable number tandem repeats," better known as VNTR's (A.R. Wyman & R. White, *A Highly Polymorphic Locus in Human DNA*, 77 PROC. NATL. ACAD. SCI. USA 6754 (1980)).

Publication of Jeffrey's work heralded the present era of exploration into the study of DNA in many disciplines. Alec J. Jeffreys et al., *Hypervariable 'Minisatellite' Regions in Human DNA*, 314 NATURE 67 (1985).

31. See David J. Werrett et al., *The Introduction of DNA Analysis Into Home Office Forensic Science Laboratories in England and Wales*, BANBURY REP. 32: DNA TECH. AND FORENSIC SCI. 233 (1989).

32. See Barry D. Gaudette, *Forensic DNA Analysis in the Royal Canadian Mounted Police*, BANBURY REP. 32: DNA TECH. AND FORENSIC SCI. 229 (1989).

33. See Xiao-Wei Zhang et al., *Restriction Fragment Length Polymorphism Analysis of Forensic Science Casework in the People's Republic of China*, 36 J. FORENSIC SCI. 531 (1991).

tionalized DNA criminal case, which catapulted DNA analysis into the public and legal spotlight.³⁴

However, this case was not the first use of DNA profiling in the forensic setting. Alec Jeffreys was also involved in a 1983 immigration case involving the son of a Ghanian woman who was a legal resident of the United Kingdom. When authorities refused to allow the boy to immigrate to the U.K., Jeffreys was able to show that there was only a one in 6×10^{-6} probability that the boy was not the woman's son. Conceding that as the world's population was only about 4 billion, authorities eventually allowed the boy to immigrate.³⁵ Thus, RFLP has found an important niche in paternity (or maternity) testing, as it correlates well with traditional methods and may be very informative in cases where traditional methods yield inconclusive or insufficient results.³⁶

Because of the tedious, time-consuming, labor-intensive and subjective procedures which require specific training in the techniques of molecular biology, RFLP is perhaps best done in research labs. Presently, there are relatively few forensic labs which use RFLP (such as Lifecodes, Cellmark, GeneScreen, the Department of Justice, and the FBI).

While someone sufficiently trained in the methodology may consistently obtain meaningful results, it is an inherently complex test system. This is probably one of the reasons why the large private labs (e.g., Cellmark and Lifecodes) are primarily molecular biology laboratories. Their forensic work is simply an offshoot of their primary efforts related to genetic testing.

Given the technical challenges³⁷ involved in the development

34. This highly celebrated British case was the subject of Joseph Wambaugh's book, *THE BLOODING* (1989). The case involved three quiet villages in Leicester, two murdered 15-year old girls, a baker named Colin Pitchfork, a colleague named Ian Kelly who passed himself off as Pitchfork in the massive DNA sample collection efforts which led to the submission of samples from 5,512 males between the ages of 13 and 30 residing in the villages, and a geneticist named Alec Jeffreys. In this case, reports indicated that the odds against two unrelated persons having the same banding pattern as the suspect and Pitchfork was about 30 billion to one. Anthony Schmitz, *Murder on Black Pad*, HIPPOCRATES, Jan-Feb. 1988, at 49.

35. For an account of this case, see Alec J. Jeffreys et al., *Positive Identification of an Immigration Test-Case Using Human DNA Fingerprints*, 317 NATURE 818 (1985); William G. Hill, *DNA Fingerprint Analysis in Immigration Test-Cases*, 322 NATURE 290 (1986); John I. Thornton, *DNA Profiling*, CHEMICAL ENGINEERING NEWS, Nov. 20, 1989, at 18.

36. Lois A. Tonelli et al., *Use of Deoxyribonucleic Acid (DNA) Fingerprints for Identity Determination: Comparison with Traditional Paternity Testing Methods—Part I*, 35 J. FORENSIC SCI. 1265 (1990); Karen R. Markowicz et al., *Use of Deoxyribonucleic Acid (DNA) Fingerprints for Identity Determination: Comparison with Traditional Paternity Testing Methods—Part II*, 35 J. FORENSIC SCI. 1270 (1990).

37. These challenges include: (1) preliminary sequencing of the DNA of interest; (2) production of oligonucleotide probes (strings of single-stranded nucleotide bases complemen-

of useful RFLP systems, it is easy to understand why molecular biologists have been involved in this type of research. While some criminalists are molecular biologists, many must return to school to learn the language and methods of molecular biology in order to become proficient. Forensic scientists, such as criminalists who conduct DNA analyses, must truly have a hybrid education—they must apply their knowledge and understanding of the forensic science world in the realm of molecular biology. They must have a good working knowledge of the legal system, particularly in areas related to the evidentiary system and testifying in court. Unlike the molecular biologist working in the research setting, criminalists must put their reputations on the line every time they testify as to their laboratory results; their techniques and methods are continuously under close scrutiny. Thus, while research molecular biologists play important and necessary roles in the development of forensic DNA tests, the members of the forensic community are in the best position to determine and designate the optimal routes to take in the ongoing collaboration of forensics and molecular biology.

B. Technology

Basically, RFLP involves (1) using restriction enzymes to chop up the DNA of interest into segments of differing sizes and molecular weights;³⁸ (2) running these DNA segments on an electrophore-

tary to the DNA of interest); (3) dealing with the vagaries of electrophoresis and "Southern" blots; (4) subjective analysis of differences in band migration through the electrophoresis gel; and (5) the infamous "band shift" frequently mentioned in RFLP court cases such as *People v. Castro*, 545 N.Y.S.2d 985 (N.Y. Sup. Ct. 1989). See also Colin Norman, *Maine Case Deals Blow to DNA Fingerprinting* 246 Sci. 1556, 1557-1558 (1989).

38. As indicated above, see *supra* note 13, most of the human genome is composed of "non-coding" DNA (DNA that does not contain the code for a protein). Within these non-coding regions, there are repetitive segments of varying lengths. These repetitive segments are called VNTRs (variable number tandem repeats) because they are composed of sequences of nucleotide bases which are repeated in tandem, any number of times. Thus, VNTRs are polymorphic—different individuals will have a different number of repeated sequences at a particular spot in the genome.

Restriction enzymes recognize specific base pair sequences and will cleave the DNA only at these particular sites. Thus, if a specific recognition base sequence is present, a restriction enzyme which recognizes that site will cleave the DNA molecule to produce fragments of a certain length. If the site is absent, a fragment of different length will be produced.

Polymorphism often results from neutral changes (changes in which mutations create or abolish recognition sites for restriction enzymes in noncoding DNA). KIRBY, *supra* note 11, at 26. Obviously, if changes occur within controlling sequences or structural genes (e.g., those which code for proteins), there may be serious phenotypic consequences (such as cystic fibrosis). *Id.*

sis gel³⁹ to separate them into "bands" based on their size and weight; (3) denaturing the DNA to make it single-stranded; (4) "blotting" the DNA onto a membrane; (5) adding radioactively-labelled DNA oligonucleotide probes complementary to a particular sequence of interest; (6) exposing the membrane to X-ray film to produce an autoradiogram; (7) observing the banding patterns produced by the radioactive probes on the autoradiogram (or "autorad"); and (8) comparing the banding patterns produced by the different test samples.

Because many DNA samples are run in different lanes on the electrophoresis gel at the same time,⁴⁰ the scientist is able to compare the migration distances of the bands in each lane separated in the gel during electrophoresis. If the banding patterns in two samples are identical, this indicates the samples may have originated from the same source.

By using various restriction enzymes, the scientist can produce different DNA segments with correspondingly different base sequences and lengths. Through sample comparisons, the use of multiple restriction enzymes, and statistical methods, the analyst determines whether the "evidence" sample was from the suspect, victim or someone else. "Direct sexing" of DNA may be used as an internal control and/or for sex determination in cases where the sex of the person is unknown.⁴¹

One major problem with RFLP that is commonly dealt with in the forensic setting is the minute amount of sample which is often the only evidence available. Current RFLP technology requires 1 to 10 g of DNA for a single analysis.

39. Electrophoresis is a technique commonly used to separate component parts of proteins, nucleic acid fragments or other molecules. In RFLP, the restriction enzyme-treated sample DNA is placed in a lane on an agarose gel (or other gel material). When an electric current is applied to the gel, the DNA fragments move through the gel at rates dependent upon such factors as their electrical charges, size and weight.

For a detailed description of the technical aspects involved in RFLP, see KIRBY, *supra* note 11, at 91-131, 135-145.

40. In addition to the samples from each person involved and any evidence samples available, a size-marker DNA cocktail is also run in one lane. This sample, containing DNA fragments of known molecular weight and size, is used as a reference to determine the number of base pairs which correspond to each band in the test sample patterns.

The "blotting" of DNA fragments from an agarose gel to a more solid support, such as a nylon membrane or cellulose acetate filter paper, for subsequent detection is called "Southern blotting," named for the researcher who originally developed the technique. See Southern, *supra* note 30, at 29.

41. Lilya V. Verbovaya & Pavel L. Ivanov, "Sexing" Deoxyribonucleic Acid (DNA) on DNA Fingerprint Gel: An Internal Control for DNA Fingerprint Evidence, 36 J. FORENSIC SCI. 991 (1991).

Blood contains 5000 to 10,000 nucleated cells per microlitre; this corresponds to 25 to 50 μg of DNA/mL. Thus bloodstains would have to contain at least 50 μL of blood to be amenable to analysis. The corresponding limit value for semen is about 10 μL . To put this latter value in context, a vaginal swab holds about 100 μL of fluid; thus semen collected on swabs cannot be diluted more than about 1:10.⁴²

This is also a problem when multiple test procedures are necessary. The decision must then be made whether to use the entire sample for RFLP analysis, or forego RFLP in favor of other analytic methods. Another consideration is that there may be an insufficient quantity of high molecular weight DNA available due to sample degradation by bacterial action, sunlight or other DNA-destroying forces. The relative stability of dried DNA has been studied in controlled experimental studies,⁴³ as well as from teeth,⁴⁴ mummy tissue and 140-year-old dried muscle.⁴⁵ In some cases, RFLP is possible.⁴⁶ However, this is not always the case, and other methods such as PCR are sometimes required.

In addition to requiring relatively large samples, RFLP has a major drawback in that it commonly involves the use of radioactive reagents, a distinct disadvantage for crime labs. Unlike most

42. George F. Sensabaugh, *Forensic Biology—Is Recombinant DNA Technology in its Future?*, 31 J. FORENSIC SCI. 393, 395 (1986).

43. Peter Gill et al., *Forensic Application of DNA Fingerprints*, 318 NATURE 577 (1985); Dwight E. Adams et al., *Deoxyribonucleic Acid (DNA) Analysis by Restriction Fragment Length Polymorphisms of Blood and Other Body Fluid Stains Subjected to Contamination and Environmental Insults*, 36 J. FORENSIC SCI. 1284 (1991); David J. Walsh et al., *Isolation of Deoxyribonucleic Acid (DNA) From Saliva and Forensic Science Samples Containing Saliva*, 37 J. FORENSIC SCI. 387 (1992); Terry L. Laber et al., *Evaluation of Four Deoxyribonucleic Acid (DNA) Extraction Protocols for DNA Yield and Variation in Restriction Fragment Length Polymorphism (RFLP) Sizes Under Varying Gel Conditions*, 37 J. FORENSIC SCI. 404 (1992); C.T. Comey & Bruce Budowle, *Validation Studies on the Analysis of the HLA-DQA Locus Using the Polymerase Chain Reaction*, 36 J. FORENSIC SCI. 1633 (1991).

44. Ted R. Schwartz et al., *Characterization of Deoxyribonucleic Acid (DNA) Obtained from Teeth Subjected to Various Environmental Conditions*, 36 J. FORENSIC SCI. 979 (1991); John S. Wayne et al., *Sensitive and Specific Quantitation of Human Genomic Deoxyribonucleic Acid (DNA) in Forensic Science Specimens: Casework Examples*, 36 J. FORENSIC SCI. 1198 (1991).

45. R. Higuchi et al., *DNA Sequences From the Quagga, an Extinct Member of the Horse Family*, 312 NATURE 282 (1984).

46. J.E. Allard, *Murder in South London: A Novel Use of DNA Profiling*, 32 J. FORENSIC SCI. SOC'Y 49 (1991); William D. Haglund et al., *Identification of Decomposed Human Remains by Deoxyribonucleic Acid (DNA) Profiling*, 35 J. FORENSIC SCI. 724 (1990); Evan Kanter et al., *Analysis of Restriction Fragment Length Polymorphisms in Deoxyribonucleic Acid (DNA) Recovered From Dried Bloodstains*, 31 J. FORENSIC SCI. 403 (1986); Alan Giusti et al., *Application of Deoxyribonucleic Acid (DNA) Polymorphisms to the Analysis of DNA Recovered From Sperm*, 31 J. FORENSIC SCI. 409 (1986); S. Pääbo, *Molecular Cloning of Ancient Egyptian Mummy DNA*, 314 NATURE 644 (1985); Higuchi *supra* note 45.

clinical laboratories, many forensic labs do not have the facilities required for isotope work.⁴⁷ Major concerns associated with the use of radioactive reagents include their cost, relatively short half-lives (while some of the radioactivity may remain for a long time, the reagent will degrade to the point where it is no longer sensitive enough for use in the test system), hazardous waste disposal considerations, the need to monitor personnel and lab space for radiation dose and contamination, and licensing regulations. If a spill occurs, it is possible that at least a portion of the laboratory will become unusable because no one will be allowed to enter the contaminated area. Due to these factors, many laboratorians are unwilling to accept the risks and disadvantages of using radioactive test methods. These concerns have helped stimulate the development of much simpler and less dangerous test methods (e.g., PCR) which utilize enzyme-based detection systems, rather than radioactive labels.

One strong advantage of RFLP is that it is possible to derive phenomenal probability statistics relating to the determination of whether a particular person is responsible for the crime under investigation. The greater the probability that the RFLP patterns observed in the evidence samples and the subject match, the greater the likelihood that the person is the one responsible for the crime.⁴⁸ There are even methods which may be used to determine the identity of a suspect who claims that another family member was responsible for the crime.⁴⁹ Thus, RFLP's "power of discrimination" is potentially very high.

Because population genetics form the basis for these determinations, there has been much research into the genetic makeup of various human subpopulations.⁵⁰ The methods used to estimate the probabilities are relatively complex. In the forensic setting, most

47. Sensabaugh, *supra*, note 42, at 396.

48. "In any case, using a single probe, . . . [t]he probability that another, unrelated individual would share exactly the same pattern is 3×10^{-11} . Add the products of a second probe, and the probability shrinks further, to 5×10^{-19} ." Roger Lewin, *DNA Fingerprints in Health and Disease*, 233 SCI. 521, 522 (1986).

In a recent appellate case, the frequency of the defendant's genotype in the Caucasian population was determined to be one in 300 million. *United States v. Jakobetz*, 955 F.2d 786, 789 (2d Cir. 1992).

49. I.W. Evett, *Evaluating DNA Profiles in a Case Where the Defence is "It was my brother,"* 32 J. FORENSIC SCI. SOC'Y 5 (1992).

50. M. Baird et al., *Allele Frequency Distribution of Two Highly Polymorphic DNA Sequences in Three Ethnic Groups and Its Application to the Determination of Paternity*, 39 AM. J. HUM. GENETICS 489 (1986); Balazs et al., *Human Population Genetic Studies of Five Hypervariable DNA Loci*, 44 AM. J. HUM. GENETICS 182 (1989). See also, Robert Gaensslen, *When Blood is Their Argument: Use and Interpretation of Genetic Marker Frequency Data in Forensic Serology*, 12 CRIME LABORATORY DIG. 75 (1985).

discussion has centered around two statistical methods. For example, the FBI uses a "fixed bin method" to establish this probability.⁵¹ The National Research Council's (NRC) Committee on DNA Technology in Forensic Science recommend the "ceiling principle" as a method which is even more conservative than the FBI's fixed bin method.⁵² As discussed below, population genetics and the statistics used to produce impressive probabilities are a subject of concern to many commentators and expert witnesses.⁵³

Perhaps, in their rush to gain court acceptance of RFLP, its advocates have been overzealous in promoting its discriminatory capabilities. It is one thing to say that there is a 1 chance in a million that this test has identified the person responsible for the crime. It may be too much for many people to comprehend that there is a 1 chance in 1,000,000,000,000. Its extraordinary claims make it somewhat suspicious, much like the promises made by the patent medicine salesman from an earlier time in our history. The claims simply seem too good to be true. Thus, association of such claims with the test method may make it much easier for the judge or jury to disregard the evidence as untrustworthy.

Although some of the distrust associated with RFLP has overflowed into the PCR arena, the concerns with PCR are much different than those associated with RFLP. Also because its power of discrimination is not as great as that of RFLP, such claims of unreliability based on skewed population genetics and statistics are not as applicable to PCR.

The Polymerase Chain Reaction (PCR)

A. History

While at Cetus, biochemist and researcher Kary Mullis conceived and began developing methods to use polymerase to produce

51. For a detailed explanation of this statistical method, see Bruce Budowle & Keith L. Monson, *A Statistical Approach For VNTR Analysis*, 1989 PROC. INT'L SYMP. FORENSIC ASPECTS DNA ANALYSIS, 121 (1989). See also, *The FBI's Response to Recommendations by the Committee on DNA Technology in Forensic Science of the National Research Council, National Academy of Science*, 19 CRIME LABORATORY DIG. 57-59 (1992).

52. NATIONAL RESEARCH COUNCIL, DNA TECHNOLOGY IN FORENSIC SCIENCE 90-93 (1992).

53. Bruce Budowle & John Stafford, *Response to Expert Report by D.L. Hartl Submitted in the Case of United States v. Yee*, 18 CRIME LABORATORY DIG. 101 (1991); Bruce Budowle & John Stafford, *Response to "Population Genetic Problems in the Forensic Use of DNA Profiles" by R.C. Lewontin Submitted in the Case of United States v. Yee*, 18 CRIME LABORATORY DIG. 109 (1991); Eric S. Lander, *Population Genetic Considerations in the Forensic Use of DNA Typing*, BANBURY REP. 32: DNA TECH. AND FORENSIC SCI. 143 (1989). See also Eric Lander, *Expert's Report in People v. Castro* (undated).

multiple DNA copies.⁵⁴ The elegant simplicity and tremendous theoretical potential of this DNA multiplication scheme has revolutionized molecular biology. Indeed, it rapidly became the method of choice of molecular biologists and others who study DNA. "While the field of forensic serology was being revolutionized by the prospect of DNA analysis, the field of molecular biology was being revolutionized by the invention of the polymerase chain reaction (PCR), which ultimately has had an impact on every area of biological science."⁵⁵ Given its utility, it is perhaps not surprising that PCR represents a significant intellectual property concern with immense economic potential.⁵⁶

54. See K. Mullis & F. Faloona, *Specific Synthesis of DNA In Vitro Via a Polymerase Catalysed Chain Reaction*, 155 METHODS ENZYMOLOGY 335 (1987); K. Mullis et al., *Specific Enzymatic Amplification of DNA in Vitro: The Polymerase Chain Reaction*, 51 COLD SPRING HARBOR SYMP ON QUANTITATIVE BIOLOGY 263 (1986); Randall K. Saiki et al., *Enzymatic Amplification of β -Globin Genomic Sequences and Restriction Site Analysis For Diagnosis of Sick Cell Anemia*, 230 SCI. 1350 (1985); Randall K. Saiki et al., *Analysis of Enzymatically Amplified β -Globin and HLA-DQ α DNA With Allele-Specific Oligonucleotide Probes* 324 NATURE 163 (1986).

55. Rebecca Reynolds et al., *Analysis of Genetic Markers in Forensic DNA Samples Using the Polymerase Chain Reaction*, 63 ANALYTICAL CHEMISTRY 1,1 (1991).

56. Cetus successfully defended two very important PCR patents (U.S. Patent Nos. 4,683,195 and 4,683,202) against Du Pont in 1991. Du Pont De Nemours & Co. v. Cetus Corp., 19 U.S.P.Q. 2d (BNA) 1174 (N.D. Cal. 1990); Du Pont De Nemours & Co. v. Cetus Corp. No. 89-2860, 1990 U.S. Dist. LEXIS 18382 (N.D. Cal. Dec. 11, 1991).

Until Cetus sold its entire GeneAmp PCR technology business to Hoffman-La Roche for an aggregate cash price of \$300 million plus royalties on future Roche PCR sales, Cetus sold PCR equipment through a joint venture with Perkin-Elmer. *Cetus To Sell PCR Business to Hoffman-La Roche for \$300 Million Plus Royalties*, BUS. WIRE, July 22, 1991, available in LEXIS/Nexis Library Bus. Wire File. PCR sales through the joint venture amounted to \$26 million for the fiscal year ending June, 1991 and were expected to grow 40-50% in 1992. Sabin Russell, *Cetus Wins Patent Case Over Du Pont: Crucial Victory For Biotech Firm*, S.F. CHRON., Feb. 28, 1991, at C1.

Cetus and Chiron Corporation recently merged to form the second largest independent biotechnology firm. The new company, worth about \$600 million in cash assets, focuses on diagnostics, vaccines, cancer therapeutics and ophthalmics. *Chiron and Cetus to Form "Second Largest" Biotech Firm*, BIOTECHNOLOGY NEWSWATCH, August 5, 1991, at 1. Almost simultaneously with the Chiron merger, Cetus sold the PCR rights to Roche. Emma Chynoweth, *Cetus Sells Diagnostics to Roche, Merges With Chiron*, CHEMICAL WK., July 31, 1991, at 12. Prior to the sale, Roche agreed to abide by the decision in a lawsuit brought against Cetus by Eastman Kodak Company to seek injunctive relief in regard to technology co-developed during the terms of an agreement between Cetus and Kodak. *Stockholders Make it Official: Chiron, Cetus to Merge, Roche Acquires PCR*, BIOTECHNOLOGY NEWSWATCH, December 16, 1991, at 1; Eastman Kodak Co. v. Cetus Corp., 1991 Del. Ch. LEXIS 151 (Del. Ch. Oct. 4, 1991); See also, Eastman Kodak Co. v. Cetus Corp., 1991 Del. Ch. LEXIS 197 (Del. Ch. Dec. 11, 1991).

Hoffman LaRoche is aggressively enforcing its rights to the large Taq market (in Europe, it was valued at \$26 million in 1991), as demonstrated by the recent suit filed against Promega. See Peter Aldhouse, *Roche Gets Tough on Illicit Sales of PCR Reagent*, 258 SCI. 1572 (1992).

While much attention has been focused on the somewhat controversial Human Genome Project, PCR is also becoming increasingly important in many other areas. Development of PCR methods led to the subsequent development of the DQ α test used in the forensic setting,⁵⁷ human immunodeficiency virus (HIV) detection and diagnostic techniques,⁵⁸ methods for the identification and detection of other microorganisms in various settings, including the aquatic environment, food, dairy, soil and clinical samples,⁵⁹ neonatal screening⁶⁰ (e.g., detection of genes associated with cystic fibrosis,⁶¹ and sickle cell anemia⁶²), identification methods for chro-

57. Henry A. Erlich et al., *The Use of the Polymerase Chain Reaction for Genetic Typing in Forensic Samples*, 1989 PROC. INT'L SYMP. FORENSIC ASPECTS DNA ANALYSIS 93; George F. Sensabaugh, *Forensic Application of the Polymerase Chain Reaction*, 31 J. FORENSIC SCI. SOC'Y 201 (1991); Rebecca Reynolds et al., *supra* note 55; Atsushi Akane et al., *Sex Identification of Forensic Specimens By Polymerase Chain Reaction (PCR): Two Alternative Methods*, 49 FORENSIC SCI. INT'L 81 (1991); Cetus Corporation, *Forensic Analysis By the Polymerase Chain Reaction (PCR)*, CETUS BACKGROUNDER, Feb. 1990; James J. Harrington, *An Evaluation of the Forensic Application of the Polymerase Chain Reaction Technique for Use in New Jersey: Legal and Scientific Considerations*, (unpublished manuscript).

58. Chin-Yih Ou, *DNA Amplification For Direct Detection of HIV-1 in DNA of Peripheral Blood Mononuclear Cells*, 239 SCI. 295 (1988); M.F. Rogers et al., *Use of the Polymerase Chain Reaction For Early Detection of the Proviral Sequences of Human Immunodeficiency Virus in Infants Born to Seropositive Mothers*, 320 NEW ENG. J. MED. 1649 (1989); M. Rayfield et al., *Mixed Human Immunodeficiency Virus (HIV) Infection in an Individual: Demonstration of Both HIV Type 1 and Type 2 Proviral Sequences By Using Polymerase Chain Reaction*, 158 J. INFECTIOUS DISEASES 1170 (1988).

59. E.J. Thomas et al., *Sensitive and Specific Detection of Listeria Monocytogenes in Milk and Ground Beef with the Polymerase Chain Reaction*, 57 APPL. ENVIRON. MICROBIOL. 2576 (1991); Henry A. Erlich et al., *Recent Advances in the Polymerase Chain Reaction*, 252 SCI. 1643, 1649 (1991); David H. Persing, *Polymerase Chain Reaction: Trenches to Benches*, 29 J. CLINICAL MICROBIOL. 1281 (1991); Richard A. Gibbs, *DNA Amplification by the Polymerase Chain Reaction*, 62 ANALYTICAL CHEM. 1202 (1990); Deborah Y. Kwoh & T. Jesse Kwoh, *Target Amplification Systems in Nucleic Acid-Based Diagnostic Approaches*, AM. BIOSCIENCES LABORATORY 14 (Oct. 1990); *Polymerase Chain Reaction Project Exploring Potential Clinical Applications*, AIDS RES. EXCHANGE, July/Aug. 1989, at 1; Ichiro Saito et al., *Detection of Epstein-Barr Virus DNA by Polymerase Chain Reaction in Blood and Tissue Biopsies From Patients with Sjogren's Syndrome*, 169 J. EXPERIMENTAL MED. 2191 (1989); Shuichi Kaneko et al., *Detection of Serum Hepatitis B Virus DNA in Patients with Chronic Hepatitis Using the Polymerase Chain Reaction Assay*, 86 PROC. NAT'L ACAD. SCI. 312 (1989).

60. Edward R.B. McCabe et al., *DNA Microextraction From Dried Blood Spots on Filter Paper Blotters: Potential Applications to Newborn Screening*, 75 HUM. GENETICS 213 (1987); Edward M. Rubin et al., *Newborn Screening by DNA Analysis of Dried Blood Spots*, 82 HUM. GENETICS 134 (1989).

61. C. Williams et al., *Same Day, First-Trimester Antenatal Diagnosis For Cystic Fibrosis By Gene Amplification*, 2 LANCET 102 (1988); A. Handyside et al., *Birth of a normal girl after in vitro fertilization and preimplantation diagnostic testing for cystic fibrosis*, 327 NEW ENG. J. MED. 905.

62. R.K. Saiki et al., *Enzymatic Amplification of β -globin Genomic Sequences and Restriction Site Analysis For Diagnosis of Sickle Cell Anemia*, 230 SCI. 1350 (1985); S.H. Embury et al., *Rapid Prenatal Diagnosis of Sickle Cell Anaemia By a New Method of DNA Analysis*,

mosomal abnormalities and specific mutations,⁶³ gene replacement therapy⁶⁴ and the development of other tests too numerous to mention.⁶⁵ PCR can even be used to determine ABO genotypes and sex.⁶⁶ The ability of PCR to amplify DNA from both a single human sperm and a diploid cell represents a major breakthrough in human pedigree analysis.⁶⁷ PCR is also useful in cases where the person is dead, but some of their tissues have been preserved in paraffin.⁶⁸ Use of these preserved samples precludes the necessity of exhumation and allows DNA analysis on those who have been cremated. PCR methods such as the AmpliType[™] DQ α kit may also be used in cases where bones are available for analysis.⁶⁹ PCR has also been used to study the epidemiology of Lyme disease, a recently recognized, yet ancient disease.⁷⁰

316 NEW ENG. J. MED. 656 (1987). PCR can also be used to diagnose many other genetic diseases, such as Huntington's disease (I. McIntosh et al., *Prenatal Exclusion Testing for Huntington Disease Using the Polymerase Chain Reaction*, 32 AM. J. MED. GENETICS 274 (1989)), and phenylketonuria (Cynthia Bottema et al., *Direct Carrier Testing for Phenylketonuria by PCR Amplification of Specific Alleles*, AMPLIFICATIONS, Mar. 1990, at 27).

63. PCR made the identification of chronic myeloid leukemia as the first cancer in which a specific genetic abnormality was identified. Ernest S. Kawasaki et al., *Diagnosis of Chronic Myeloid and Acute Lymphocytic Leukemias by Detection of Leukemia-Specific mRNA Sequences Amplified In Vitro*, 85 PROC. NAT'L ACAD. SCI. USA 5698 (1988).

64. Mark R. Hughes & C. Thomas Caskey, *Medical Genetics*, 265 JAMA 3132 (1991).

65. For an excellent review of the applications of PCR in medical diagnostics for genetic diseases, see Barry I. Eisenstein, *The Polymerase Chain Reaction, New Method of Using Molecular Genetics for Medical Diagnosis*, 322 NEW ENG. J. MED. 178 (1990). See also, Shirley Kwok & John Sninsky, *Application of PCR to the Detection of Human Infectious Diseases*, in PCR TECHNOLOGY 235 (Henry A. Ehrlich ed., 1989).

For an excellent recent overview of PCR and its multitude of applications, see Henry A. Erlich et al., *supra* note 57.

66. James Chun-I Lee & Jan-Gowth Chang, *ABO Genotyping by Polymerase Chain Reaction*, 37 J. FORENSIC SCI. 1269 (1992); Rebecca Reynolds, *Rapid Determination of Gender Using the Polymerase Chain Reaction*, Paper presented at the 77th Semi-Annual Seminar of the California Association of Criminalists (May, 1991).

67. Honghua Li et al., *Amplification and Analysis of DNA Sequences in Single Human Sperm and Diploid Cells*, 335 NATURE 414 (1988).

68. Darryl Shibata et al., *Fixed Human Tissues: A Resource for the Identification of Individuals*, 36 J. FORENSIC SCI. 1204 (1991); Darryl Shibata et al., *Human Immunodeficiency Viral DNA Is Readily Found in Lymph Node Biopsies from Seropositive Individuals*, 135 AM. J. PATHOL. 697 (1989); and Eric C.J. Claas et al., *Human Papillomavirus Detection in Paraffin-Embedded Cervical Carcinomas and Metastases of the Carcinomas by the Polymerase Chain Reaction*, 135 AM. J. PATHOL. 703 (1989).

69. M.N. Hochmeister et al., *Typing of Deoxyribonucleic Acid (DNA) Extracted From Compact Bone From Human Remains*, 36 J. FORENSIC SCI. 1649 (1991).

70. David H. Persing et al., *Detection of Borrelia burgdorferi DNA in Museum Specimens of Ixodes dammini Ticks*, 249 SCI. 1420 (1990); and David H. Persing, *Borrelia, Babesia, Yersinia: Emerging Blood-Borne Pathogens*, Paper Presented at the American Society for Microbiology, Northern California Branch and Northern California Association of Public Health Microbiologists, 8th Annual Combined Fall Conference (Oct. 1992).

PCR has been a major factor in the development of the newly-formed fields of molecular anthropology⁷¹ and molecular paleontology,⁷² in which evolutionary relationships between species and the development of modern organisms are investigated.⁷³ PCR is even being used to monitor environmental contamination,⁷⁴ establish the new medical field of diagnostic molecular pathology,⁷⁵ and to help identify those killed in the recent conflict in the Persian Gulf.⁷⁶ The tremendous contributions which PCR has made in so many areas related to molecular biology led to its designation as "Molecule of the Year" in 1989 by Science, a leading scientific journal.⁷⁷

B. Technology

PCR is based on a very simple idea. Perhaps the most appropriate analogy for PCR is as a genetic photocopy machine.⁷⁸ The PCR amplification system simply takes advantage of the natural DNA replication system and manipulates it to the advantage of the analyst to produce many millions of DNA copies.

71. David A. Lawlor et al., *Ancient HLA Genes From 7,500 Year-Old Archaeological Remains*, 349 NATURE 785 (1991); S. Pääbo et al., *Mitochondrial DNA Sequences From a 7000-Year Old Brain*, 16 NUCLEIC ACIDS RES. 9775 (1988); S. Pääbo, *Ancient DNA: Extraction, Characterization, Molecular Cloning, and Enzymatic Amplification*, 86 PROC. NAT'L ACAD. SCI. USA 1939 (1989); Erika Hagelberg et al., *Ancient Bone DNA Amplified*, 342 NATURE 485 (1989); Ulf B. Gyllensten & Henry A. Erlich, *Ancient Roots for Polymorphism at the HLA-DQA Locus in Primates*, 86 PROC. NAT'L ACAD. SCI. USA, 9986 (1989); and Philip E. Ross, *Eloquent Remains*, SCI. AM., May, 1992, at 115. See also, Thomas J. White et al., *The Polymerase Chain Reaction*, 5 TRENDS IN GENETICS 185 (1989); Leslie Roberts, *How to Sample the World's Genetic Diversity*, 257 SCI. 1204 (1992)..

72. Jared M. Diamond, *Old Dead Rats Are Valuable*, 347 NATURE 334 (1991); Svant Pääbo & Allan C. Wilson, *Polymerase Chain Reaction Reveals Cloning Artefacts*, 334 NATURE 387 (1988); and D. Janczewski et al., *Molecular Phylogenetic Inference From Saber-Toothed Cat Fossils of Rancho La Brea*, 89 PROC. NAT'L ACAD. SCI. USA 9769 (1992).

73. Bryan Sykes, *The Past Comes Alive*, 352 NATURE 381, 382 (1991).

74. Asim K. Bej et al., *Detection of Coliform Bacteria in Water By Polymerase Chain Reaction and Gene Probes*, 56 APPLIED ENVTL. MICROBIOL. 307 (1990); Asim K. Bej et al., *Detection of Escherichia coli and Shigella spp. in Water Using the Polymerase Chain Reaction and Gene Probes*, 57 APPLIED ENVTL. MICROBIOL. 1013 (1991); Asim K. Bej et al., *Detection of Viable Legionella pneumophila in Water By Polymerase Chain Reaction and Gene Probe Methods*, 57 APPLIED ENVTL. MICROBIOL. 597 (1991).

75. W.W. Grody et al., *Diagnostic Molecular Pathology*, 2 MOD. PATHOLOGY 553 (1989).

76. George W. Clarke, 'Genetic Fingerprinting' Grows as Important Forensic Tool, L. ENFORCEMENT Q., May-June-July 1991, at 5, 28.

77. Daniel E. Koshland, *The Molecule of the Year*, 246 SCI. 1541 (1989); Ruth L. Guyer & Daniel E. Koshland, *The Molecule of the Year*, 246 SCI. 1543 (1989).

"Like the radio telescope and electron microscope, it represents an advance of a fundamental nature." J. Madeleine Nash, *Ultimate Gene Machine*, TIME, August 12, 1991, at 54, 56.

78. Robert Keeler, *Uses for PCR Are Multiplying in Gene-Related Research*, 30 RES. DEV., Aug. 1991, at 30.

To accomplish this, DNA is extracted from the test sample and combined with a mixture of the heat-stable DNA polymerase (*Taq*) originally obtained from a hot springs bacterium (*Thermus aquaticus*) and all of the building blocks necessary for DNA replication, including nucleotides and primers.⁷⁹

A machine, such as the Perkin-Elmer thermal cycler,⁸⁰ is used to heat the sample DNA. Heating causes the bonds between the bases to break, separating the molecule into two strands (the DNA is "denatured"). This allows the primers to bind ("anneal") to the complementary sequences on the single-stranded template DNA strands. DNA polymerase then works from the site of the annealed primer-template and catalyzes the synthesis of new DNA strands by linking nucleotides together in the precise order specified by the template DNA strands. This is termed "extension." The cycle of denaturation, annealing and extension is then repeated as many times as necessary to produce the desired number of DNA copies.⁸¹ Under highly "stringent" conditions, the *Taq* polymerase is able to very faithfully reproduce the DNA molecule.⁸² Thus, the amplifi-

79. Primers are segments of DNA with known sequences, designed and produced by the researcher so that they will bind ("anneal") to the DNA sequences which flank the section of DNA of interest in the sample to be amplified. When they are bound to the DNA, the primers serve as signals for the DNA polymerase to attach to the DNA and begin forming the complementary strands.

80. The Perkin-Elmer DNA Thermal Cycler is a microprocessor-controlled, thermal cycling instrument which automates the rapid and precise temperature changes needed in the PCR process. User-programmable files and preprogrammed protocols can be used. The sample holding block will accommodate 48 0.5 L microcentrifuge reaction tubes. The temperature range is -50C to 1000C. PERKIN-ELMER CETUS, DNA THERMAL CYCLER 480 SALES BROCHURE 8-9 (1990).

81. In the DQ α test kit, the program of denaturation, annealing and extension is repeated for 30 cycles. CETUS AMPLITMTYPETM HLA DQ α FORENSIC DNA AMPLIFICATION & TYPING KIT, PACKAGE INSERT 13 (undated) [hereinafter AMPLITMTYPETM PACKAGE INSERT].

82. This works because the hydrogen bonds between incorrectly paired bases (such as adenine and cytosine, for example) are too weak to withstand the heat. Thus, if the DNA polymerase made a mistake and tried to pair the wrong base to the parent DNA strand, the base would "fall off" and either DNA replication would be halted at this point or the correct base would be added before the DNA polymerase moved on down the molecule.

The rate at which the AmpliTaqTM DNA polymerase (the *Taq* polymerase included with the DQ α test kit) misincorporates nucleotides (inserts an incorrect base while it is extending a DNA chain) is estimated to be from 1 per 10,000 to 1 per 200,000 incorporated nucleotides per replication cycle.

Using a "worst case" (mutation rate assumptions of 1 in 10,000, 32 doublings at 100% efficiency and the fewest number of replicates which can be detected in the AmpliTypeTM Kit), no more than 1 product molecule in 50 could have a replication error in the region of an allele specific oligonucleotide probe. (A more reasonable estimate is 1 molecule in 500, and even this low probability is based on "worst case" assumptions). The probability of such an error converting one allele to another in a probe region is even lower: even if such an

cation products truly reflect the content of the original DNA sample. Prior to the detection steps described below, the amplified DNA is again denatured. This allows the "oligonucleotide-specific DNA probes" to bind to complementary sequences which may be present in the sample of amplified DNA.

Detection of the DNA of interest in the test sample is accomplished with these oligonucleotide-specific probes which are composed of DNA strands complementary to those of the DNA of interest.⁸³ In most common test systems, including the Ampli-Type[®] DQ α test kit, a "dot" of each probe correlating to the DNA sequence of each allele under investigation is attached to a nylon membrane at a distinct location.⁸⁴ Under suitably stringent conditions, the probe captures complementary amplified DNA; the probe will not bind to any non-complementary DNA sequences. This characteristic greatly contributes to the test's high degree of specificity.

In the DQ α test kit and many other test systems, the detection component is comprised of three molecules—biotin, streptavidin, and horseradish peroxidase.⁸⁵ Biotin is bound to the primers while the streptavidin and horseradish peroxidase are used together as an "enzyme conjugate." This conjugate is added during the final steps of the test procedure. Biotin has an extremely strong affinity and is highly specific for streptavidin.⁸⁶ Thus, if the DNA in the sample and its attached primer is bound to the probe, the horseradish per-

error were to occur in the first amplification cycle, it would not generate a detectable signal using this amplification and typing procedure.

CETUS CORPORATION, AMPLI-[®]TYPE USER GUIDE 6-30 (version 2, 1990) [hereinafter USER GUIDE].

83. Thus, if the sequence in the amplified DNA is ATTCG, the probe sequence will be TAAGC.

84. This is called a "reverse dot-blot." R.K. Saiki et al., *Genetic Analysis of Amplified DNA With Immobilized Sequence-Specific Oligonucleotide Probes*, 86 PROC. NATL. ACAD. SCI. USA 6230 (1989). In the original DQ α test kit, the sample DNA was dotted onto nylon membrane strips held within individual wells; different solutions, each containing a different probe was added to each strip. This is called a "dot blot." R.K. Saiki et al., *Analysis of Enzymatically Amplified β -Globin and HLA-DQ α With Allele-Specific Oligonucleotide Probes*, 324 NATURE 163 (1986); Catherine T. Comey, *The Use of DNA Amplification in the Analysis of Forensic Evidence*, 15 CRIME LABORATORY DIG. 99 (1988).

There is an inherently much greater chance of human error involved in the dot blot procedure. Care must be used to properly and thoroughly label each well and add the correct probe solutions. In the DQ α test kit reverse dot-blot format, the kit is supplied with each of the probe DNAs bound to membrane strips. Thus, the analyst just needs to add the test DNA to the strip. While labelling and care should be used with this test also, there are fewer steps involved, thereby decreasing the amount of manipulation required.

85. Radioactive probes, such as those used for RFLP, are used by some researchers.

86. Meir Wilchek & Edward A. Bayer, *The Avidin-Biotin Complex in Immunology*, 5 IMMUNOLOGY TODAY 39 (1984). See also, Pennina R. Langer et al., *Enzymatic Synthesis of*

oxidase reacts with a soluble, colorless compound tetramethylbenzidine (TMB), to produce an insoluble blue product. The allelic composition of the sample DNA is indicated by the presence of blue spots on the nylon membrane. In addition to the "test" spots used to identify the discrete alleles, there is also a "control" spot which will turn blue if the DQ α genes have been amplified. The intensity of each test dot is compared with that of the control spot; if the control dot is not present, the test is deemed unreadable.⁸⁷

There are several important considerations which must be kept in mind while developing PCR technology for use in genetic marker detection in the forensic setting. As listed below, various criteria have been expounded:

In order to be of maximum benefit to the forensic scientist, a genetic marker system for forensic PCR analysis should satisfy the following criteria:

1. The marker should be highly polymorphic and have a high level of genetic heterozygosity.
2. The target sequence should be easily and specifically amplified.
3. Methods for detecting allelic variation should be uncomplicated and thoroughly reliable.
4. Population data on genotype frequencies must be available in order to assign estimates of the marker's power of discrimination and the probability of false inclusion.
5. The marker systems should be inherited independently so that frequencies derived from one marker system can be multiplied with those from others, thereby increasing the power of discrimination. Independent inheritance occurs when the markers are on separated chromosomes or are in linkage equilibrium when present on the same chromosome.⁸⁸

Presently, there are very few test systems which have been sufficiently developed for forensic use. The most well-known is the AmpliType[™] DQ α test kit.⁸⁹ While AmpliTaq[™] (the *Taq*

Biotin-Labeled Polynucleotides: Novel Nucleic Acid Affinity Probes, 78 PROC. NATL. ACAD. SCI. USA 6633 (1981).

87. See USER GUIDE, *supra* note 82, at 4-1. Dots with signals less than the "C" dot should be interpreted with caution.

88. Cecilia H. von Beroldingen et al., *Applications of PCR to the Analysis of Biological Evidence*, in PCR TECHNOLOGY: PRINCIPLES & APPLICATIONS FOR DNA AMPLIFICATION 209, 210 (Henry A. Erlich ed., 1989).

89. Another test system used by some companies detects polymorphisms within a related locus, DQ β . This test system takes advantage of many of the same reagents as the DQ α .

polymerase) is the subject of patents,⁹⁰ the primer and probe sequences are not proprietary.⁹¹ Thus, unlike the proprietary probes used in RFLP (e.g., the probes developed by Jeffreys), the sequences of these molecules are available for any scientist to produce and test.

In the AmpliType[™] test kit, a specific portion of the human genome which is known to code for particular structures on white blood cells ("leukocytes") is amplified and used to "type" the person being studied.⁹² The human leukocyte antigen system (HLA) is the area of interest in the AmpliType[™] kit. This kit has been developed and refined to the point where a trained person can use the necessary equipment and the reagents provided in the kit, easily follow the established protocol and obtain useful results. Importantly, this area of the human genome has been extensively studied due to its role in immune system function.

C. The Human Leukocyte Antigen System (HLA)

The HLA system is composed of proteins (or "antigens") which are coded for by a large number of genetic loci present on

kit, such as the *Taq* polymerase and the thermal cycler. Different probes and primers are used to detect allelic variations within the β subunit of the DQ molecule, instead of the α subunit which is the basis of the Cetus DQ α test kit.

GeneScreen of Dallas, Texas was the major company utilizing DQ β . Linda Carrico, *Texas' First Forensic Lab Set to Open in Dallas*, 4 TEX. LAW. 1 (1989). However, they have recently switched to the more well-known DQ α test kit. Telephone Interview with Robert Giles, Scientific Director, *Gene Screen* (Dec. 1991).

90. *Taq* DNA polymerase and AmpliTaq[™] DNA polymerase are covered by U.S. Patent No. 4,889,818, assigned to Cetus Corporation. Cetus is also the assignee of the GeneAmp[™] PCR Process covered by U.S. Patent Nos. 4,683,202; 4,683,195; 4,800,159; and 4,965,188.

91. The probe sequences of the Cetus DQ α test kit are published in USER GUIDE, *supra* note 82, at Figure 1-4.

92. These structures are called "antigens." Antigens are recognized by antibodies, the small proteins produced by a sub-group of white blood cells known as B lymphocytes or B-cells. Antibodies are extremely important in the proper functioning of the immune system and help the body recognize "foreign" antigens, such as those contained on viruses and bacteria. They also help in the recognition and potential elimination of abnormal tissue cells, including malignant and senescent cells.

Tissue typing is used to determine which array of antigens are present in the tissue; this is of utmost importance in transplantation and other medical procedures. If someone receives an organ from a donor of a different type, it is very likely that the recipient will reject the transplanted organ, often leading to other complications and death. Therefore, it is very important that the tissue type of both the donor and recipient be determined before any transplantation attempts are made. Tissue typing is also often used in paternity investigations.

Thus, PCR DQ α typing can be considered tissue typing on a genetic level, instead of at the antigenic level. PCR simply goes straight to the source of the code.

chromosome #6.⁹³ Due to the large number of allelic variations in these proteins, there is a large degree of polymorphism.⁹⁴ The HLA proteins are divided into two structurally and functionally distinct groups—Class I and Class II.⁹⁵ Within Class II, there are three families of proteins—DP, DQ and DR.⁹⁶ Each of these Class II proteins is composed of two subunits, “ α ” and “ β ,” which are separately encoded in the DNA of each gene cluster.⁹⁷ HLA DQA1 is the gene which codes for the α subunit.⁹⁸

Within DQ α , there are eight different alleles and one “pseudogene.”⁹⁹ The “major” alleles, DQA 1, 2, 3 and 4, differ from one another at many nucleotide positions; they are easily dif-

93. Karen A. Sullivan & Bernard Amos, *The HLA System and Its Detection*, in *MANUAL OF CLINICAL LABORATORY IMMUNOLOGY* 835, 835 (Noel R. Rose et al. eds., 1986).

94. *Id.*

95. *Id.* at 835-837. The Class I antigens are present on the membranes of most nucleated cells and are recognized as the classical tissue transplantation antigens (“histocompatibility antigens”). Benjamin D. Schwartz, *The Human Major Histocompatibility HLA Complex*, in *BASIC & CLINICAL IMMUNOLOGY* 55, 59 (Daniel P. Stites et al. eds., 5th ed. 1984). The Class II proteins are found on the immune system cells. These proteins are very important in bone marrow transplantation and autoimmune diseases.

Autoimmune diseases are diseases which are caused by the attack of the body's immune system on the body itself. Examples of these very destructive diseases include systemic lupus erythematosus (SLE), pernicious anemia, rheumatoid arthritis, juvenile diabetes, and others. JOHN W. KIMBALL, *INTRODUCTION TO IMMUNOLOGY* 494 (2d ed., 1986); and Henry A. Erlich & Teodorica L. Bugawan, *HLA Class II Gene Polymorphism: DNA Typing, Evolution, and Relationship to Disease Susceptibility*, in *PCR TECHNOLOGY: PRINCIPLES & APPLICATIONS FOR DNA AMPLIFICATION* 201 (Henry A. Erlich ed., 1989).

96. Sullivan & Amos, *supra* note 93, at 836.

97. *Id.*

98. The World Health Organization developed a new nomenclature system for these antigens. This comment uses the old nomenclature simply to avoid confusion with much of the literature which also uses the old nomenclature.

The new nomenclature, shown in the table below for the protein, gene and various alleles associated with the locus, was adapted from WHO, *Nomenclature for Factors of the HLA System*, 1989, 31 *IMMUNOGENETICS* 131 (1990).

	Nomenclature used in this review	WHO revised nomenclature
Protein	DQ α	DQ α
Gene	DQ α	DQA1
Allele	DQA 1.1	DQA1*0101
	DQA 1.2	DQA1*0102
	DQA 1.3	DQA1*0103
	DQA 2	DQA1*0201
	DQA 3	DQA1*0301
	DQA 4.1	DQA1*0501
	DQA 4.2	DQA*0401
	DQA 4.3	QA*0601
Pseudogene	DX α	DQA2

99. Pseudogenes are nonfunctional gene copies which remain in the genome, although

ferentiated by one probe sequence.¹⁰⁰ There are also subtypes within 1 (1.1, 1.2, 1.3) and 4 (4.1, 4.2, 4.3). Although these subtypes differ from each other by only one or a few nucleotides, they will all bind with the probe for the major type (i.e., 1.1, 1.2, and 1.3 will all bind with the probe for 1); the 1 subtypes are distinguished by using additional probes specific to the correspondingly different sections for each allele.¹⁰¹ While 4.1, the most common type 4 allele, can be distinguished from 4.2 and 4.3, these other alleles are relatively rare and are identical to each other in the sequence detected by the AmpliType[™] HLA DQ α test system.¹⁰² Therefore, because 4.2 and 4.3 are not included, the test system only makes use of the six most important alleles.

Following PCR amplification of the evidence samples, the DQ α types are compared. If the DQ α genotype of the suspect is different from that of the evidence sample, the suspect is "excluded" and cannot be the donor of the evidence. Unlike matches or inclusions, exclusions are independent of the frequencies of the genotype in the population.¹⁰³

If the suspect and evidence have the same genotype, then the suspect is "included" as a possible source of the evidence sample. The probability that another, unrelated individual would also match the evidence is equal to the frequency of that genotype in the relevant population. Multiple studies have been conducted to determine the genotype frequencies in various ethnic and geographically-defined population groups; significant differences were observed between the ethnic groups examined.¹⁰⁴

they may have recently lost their function in evolution. See, USER GUIDE,*supra* note 82, at 1-3.

100. R. Saiki et al., *Genetic Analysis of Amplified DNA With Immobilized Sequence-Specific Oligonucleotide Probes*, 86 PROC. NAT'L ACAD. SCI. USA 6230 (1989).

101. USER GUIDE, *supra* note 82, at 1-3.

102. *Id.*

103. *Id.* at 5-1.

104. In a recent study, over 1400 individuals were typed using both the dot-blot and reverse dot-blot methods to determine the DQ α genotypes for 11 population groups. The observed frequencies of DQ α genotypes did not significantly deviate from those expected on the assumption of Hardy-Weinberg equilibrium. There was a slight excess of homozygotes in one Hispanic (denoted by "Spanish surname") and one Southeast Asian group which was found to be consistent with the heterogeneity of these groups. These data indicate that the HLA-DQ α marker system is useful in individual identification because genotype frequencies can be reliably estimated from allele frequency data. Rhea Helmuth et al., *HLA-DQ α Allele and Genotype Frequencies in Various Human Populations, Determined Using Enzymatic Amplification and Oligonucleotide Probes*, 47 AM. J. HUM. GENETICS 515 (1990).

D. Population Genetics and the DQ α Level of Discrimination

As stated above, in order to develop PCR kits, (e.g., AmpliType[™]), it is necessary to identify all of the possible alleles which could be present at the locus of interest, determine their DNA sequences and then study large populations to determine the frequencies of each allele and genotype for various ethnic groups.¹⁰⁵ These population genetics data are used to determine the statistical probabilities that a certain person within a particular racial group will have a particular combination of HLA DQ α alleles. As discussed in more detail below, the DQ α system is more discriminating than any of the traditional genetic markers used in forensics.¹⁰⁶

For example, each person has two DQA alleles (one contributed from each parent) and there are a total of six alleles detected in the AmpliType[™] system. Thus, there are 21 potential genotypes which may be detected. The frequencies of these genotypes range from less than 0.0005 to 0.15.¹⁰⁷ The discriminating power (DP) of the DQ α typing system is 0.93.¹⁰⁸ This compares favorably with the discriminating power of the ABO red cell typing system (DP = 0.60), and analysis of the isozyme PGM (phosphoglucomutase) (DP = 0.76).¹⁰⁹ From these numbers, it is evident that, by itself, PCR DQ α typing can neither provide individual identification nor achieve the phenomenally high numbers generated by RFLP methods. However, it has proved useful in conclusively including or excluding criminal suspects in circumstances where conventional typing has failed or insufficient DNA was available for RFLP.¹¹⁰

There are some distinct advantages to PCR over RFLP. Unlike presently used RFLP systems, it is an allele-specific system which identifies a discrete trait inherited in a clear Mendelian fashion. The distinctness and permanence of the DQ α allelic variants is clearly demonstrated by their maintenance over millions of years.¹¹¹ Comparison of the observed genotype frequencies with the Hardy-

105. *Id.*; See also, Sara A. Westwood & David J. Werrett, *An Evaluation of the Polymerase Chain Reaction Method for Forensic Applications*, 45 FORENSIC SCI. INT'L 201 (1990).

106. George F. Sensabaugh & Cecilia von Beroldingen, *The Polymerase Chain Reaction: Application to the Analysis of Biological Evidence*, in FORENSIC DNA TECHNOLOGY 63, 72 (Mark A. Farley & James J. Harrington eds., 1991).

107. von Beroldingen et al., *supra* note 88, at 212.

108. Discriminating power is the probability of distinguishing between two randomly selected individuals from all of the populations studied.

109. Sensabaugh & von Beroldingen, *supra* note 106 at 212.

110. See, e.g., *People v. Quintanilla*, No. C-23691 (San Mateo Superior Ct., Aug. 16, 1991). For a discussion of this case, see *supra* note 8.

111. Gyllensten & Erlich, *supra* note 71.

Weinberg expected frequencies can help validate typing methods—an excess of homozygosity would reveal a population substructure.¹¹² The close fit between the observed and expected DQ α genotype frequencies affirms the typing methodology and genetic model.

Thus, although the discrimination power for the DQ α marker system is less than that for most RFLP systems, it is a simple and rapid method which is capable of analyzing minute and degraded samples. As more PCR-based markers are researched and become readily available, a panel of tests will likely be developed which, in addition to the exclusionary value already provided by the DQ α system, will provide valuable information for individual inclusions.

Alone, the AmpliType[™] system for DQ α provides a power of discrimination of approximately 83 to 94%.¹¹³ However, because the DQ α alleles are inherited independently from the conventional marker systems, results can be combined to increase the overall power of discrimination. Thus, combining the individualization potentials for DQ α , ABO, PGM and secretor status in a typical sexual assault case increases this power of discrimination to 99%.¹¹⁴

The following table is from an informational flyer provided by Cetus, which illustrates how DQ α test results can be presented in court in conjunction with results from conventional genetic marker typing in a typical sexual assault case.

112. Helmuth et al., *supra* note 104, at 521.

The assumption of Hardy-Weinberg equilibrium allows estimation of genotype frequencies from observed allele frequencies and makes high levels of individual discrimination possible from relatively limited population data. For many VNTR (variable number tandem repeat) or RFLP systems, the discrimination of alleles is limited by gel electrophoresis resolution. A great excess of homozygotes may be found in VNTR population samples. Eric Lander, *DNA Fingerprinting on Trial*, 339 NATURE 501 (1989). The inability to fully discriminate classes due to limitations of the typing methodology and potential subpopulation structure may contribute to an excess of homozygotes. High mutation rates in some VNTR systems also creates the expectation of homozygote excess (up to 5%). Alec Jeffreys et al., *Spontaneous Mutation Rates to New Length Alleles at Tandem Repetitive Hypervariable Loci in Human DNA*, 332 NATURE 278 (1988).

113. Helmuth et al., *supra* note 104, at 520.

114. See Sensabaugh, *Biochemical Markers of Individuality*, in FORENSIC SCIENCE HANDBOOK 338-415 (Richard Saferstein ed., 1982).

Sample	ABO/Secretor Status	PGM	HLA DQ α
Victim Reference Blood	O Secretor	1+	1.2,1.2
Vaginal Swab	A & H Activity	1+1—	1.3,2 (Sperm) 1.2,1.2 (Epithelial cells)
Questioned Hair From Victim's Pubic Combing	Not Done	Not Done	1.3,2
Suspect Reference Blood	A Secretor	1+1—	1.3,2

The results in the above hypothetical case indicate that the suspect cannot be excluded because the semen contributor is an ABO Type A Secretor with PGM type 1+1— or 1— activity and DQ α type 1.3,2. Without including DQ α gene frequency information, this combination of types occurs in approximately 7% of the white population.¹¹⁵ But, if DQ α gene frequency information is included, the combination of types occurs in approximately 0.09% of the white population.¹¹⁶ Furthermore, the suspect is also not excluded as the source of the questioned pubic hair. DNA extracted from the hair root was 1.3,2, which is consistent with the DQ α type of the suspect. This DQ α genotype occurs in approximately 1.9% of the white population, a genotype frequency less common than that of the conventional ABO, PGM and secretor systems combined.

Recognizing the great potential in combining PCR with RFLP or direct sequencing, many researchers are studying the possibilities.¹¹⁷ The combination of PCR and RFLP affords a greater detection sensitivity than can be achieved by the RFLP method alone and greater discrimination than can be achieved by PCR alone.¹¹⁸ This is a very powerful combination of methods which could result

115. B.W. Grunbaum et al., *Distribution of Genetic Frequencies and Discrimination Probabilities for 22 Human Blood Genetic Systems in Four Racial Groups*, 25 J. FORENSIC SCI. 428 (1980).

116. *Id.*

117. K. Kasai et al., *Amplification of VNTR Locus (pMCT118) by the Polymerase Chain Reaction (PCR)*, 1989 PROC. INT'L SYMP. FORENSIC ASPECTS DNA ANALYSIS 279 (1989); Bruce Budowle et al., *Analysis of the VNTR Locus DIS80 by PCR Followed by High-Resolution PAGE*, 48 AM. J. HUM. GENETICS 137 (1991); David R. Engelke et al., *Direct Sequencing of Enzymatically Amplified Human Genomic DNA*, 85 PROC. NAT'L ACAD. SCI. USA 544 (1988).

118. See, Bruce Budowle et al., *Review Article: An Introduction to the Methods of DNA Analysis Under Investigation in the FBI Laboratory*, 15 CRIME LABORATORY DIG. 8,18 (1988). Also see, *Proceedings of the International Seminar on the Forensic Application of PCR*

in another generation of DNA typing methods.¹¹⁹

E. Perceived Problems Associated with PCR

In addition to the low level of discrimination, as discussed above, there are several perceived problems with PCR. However, while some of these problems are of valid concern, others appear to be make-weight legal arguments against the use of the technology. Concerns voiced in the literature and cases include:

- (1) "allelic drop-out";
- (2) the sensitivity of the test and the potential for contamination;
- (3) the small number of laboratories conducting the test; and
- (4) interpretation problems.

1. "Allelic Drop-Out"

This is a term which has been used to describe differential or preferential amplification, the situation in which the procedure greatly favors one of the two alleles present in a heterozygous individual such that the results would lead one to wrongly conclude that the individual was homozygous at the locus examined.¹²⁰ However, there is no scientific basis for the belief that differential amplification occurs in the AmpliType[™] system.

First, there is no evidence that selective priming for some alleles relative to other alleles occurs in the AmpliType[™] system.¹²¹ However, an alternative explanation is that there is selective denaturation of some alleles relative to others. An experiment was conducted on DNA from a DQ α 1.1,4 heterozygote to determine whether selective denaturation occurs.¹²² At 90°C or above, there

Technology, 18 CRIME LABORATORY DIG. (1991), and Bruce Budowle, *AMP-FLPs: Genetic Markers for Forensic Identification* 18 CRIME LABORATORY DIG. 134 (1991).

119. Amplified restriction fragment length polymorphisms (AmpFLPs) are recently developed test systems in which a DNA sample too small for conventional RFLP analysis is first amplified and then tested by RFLP. G.T. Horn et al., *Amplification of a Highly Polymorphic VNTR Segment by the Polymerase Chain Reaction*, 17 NUCLEIC ACIDS RES. 2140 (1989); E. Boerwinkle et al., *Rapid Typing of Tandemly-Repeated Hypervariable Loci by the Polymerase Chain Reaction: Application to the Apolipoprotein B 3' Hypervariable Region*, PROC. NAT'L ACAD. SCI. 212 (1989). A test kit for D1S80 is currently available. This kit may become the first AMP-FLP kit used for forensic purposes. See Kasai et al., *supra* note 28, and Y. Nakamura et al., *Isolation and mapping of a polymorphic DNA (pMCT118) on chromosome 1p (Dis80)*, 16 NUCLEIC ACIDS RES. 9364 (1988). This method not only takes advantage of the exquisite sensitivity of PCR, but it also minimizes the problems of bacterial DNA contamination, and increases the quantity of sample DNA so that RFLP is possible.

120. USER GUIDE, *supra* note 82, at 6-24.

121. *Id.* See also Gyllenstein & Erlich, *supra* note 71.

122. The sequences of DAQ 1.1, 1.2 and 1.3 alleles significantly differ from the DQA 2,3,

was consistent typing of DQ α 1.1 and 4. Below 88°C, neither allele amplified nor typed. However, at 88°C, the results reflected preferential amplification of DQA 4 as compared to DQA 1.1 (DQA 4 allele could be amplified, but not DQA 1.1). These results are based on the ability of the DQA 4 allele to be denatured and serve as a template at this low temperature.

Therefore, preferential amplification and hence, allelic dropout is a possibility if the temperature of the reaction is substantially below the specified temperature of 94°C. If the temperature of the thermal cycler wells is close to 94°C during denaturation, preferential amplification and "allelic dropout" should not occur.¹²³ Thus, this important study indicated that the phenomenon is possible, but improbable, as long as the equipment is properly calibrated and maintained. Therefore, as an additional control, the kit presently on the market contains a heterozygous human genomic DNA control of DQ α type 1.1,4.

Also, the population genetics data do not reveal an excess of homozygotes which would be attributable to some hypothetical "blank" or "null" allele that might fail to amplify.¹²⁴ In addition, as the oligonucleotide primers are capable of amplifying a specific DQ α fragment from many different primate species, the sequences to which the primers are complementary are highly conserved in evolution.¹²⁵ Thus, allelic drop-out is a "non-problem" which a proponent of PCR evidence should be able to discuss if the opponent of the evidence brings it up.

2. Sensitivity and Contamination

The exquisite sensitivity of PCR is both its blessing and its curse. PCR has the capability to amplify the DNA present in a single hair root,¹²⁶ including several-month-old fallen hairs in

and 4 alleles in that they have a higher GC to AT base pair ratio. USER GUIDE, *supra* note 82, at 6-24. This is significant in denaturation because there are three hydrogen bonds between GC pairs and only two bonds between AT pairs. See LEWIN, *supra* note 9, at 17-24. Thus, higher temperatures (more energy) are required to break GC bonds than AT bonds. The experiment was designed to determine whether, under non-standard conditions, preferential amplification occurs due to the selective denaturation of some alleles.

123. USER GUIDE, *supra* note 82, at 6-24.

124. Helmuth et al., *supra* note 104, at 520.

125. Gyllenstein & Erlich, *supra* note 71.

126. Russell Higuchi et al., *DNA Typing From Single Hairs*, 332 NATURE 543 (1988). In this publication, the authors indicate that the DNA in hair is often limited and/or degraded. *Id.* at 544. This does not appear to be a major problem for PCR, but would preclude the use of RFLP.

The use of hair samples has various advantages over the use of blood. Some suspects may be unwilling to provide blood for testing due to their religious beliefs or customs. In

which DNA was not detectable by the usual chemical methods (representing less than 1 ng DNA).¹²⁷ This is of particular significance because hair is one of the most frequently found forms of biological evidence at crime scenes.¹²⁸

Given this extreme sensitivity, one major concern is that "contaminating" DNA present in the sample will be amplified and completely mask the true DNA of interest.¹²⁹ However, there are many routes by which such contaminating DNA may be avoided, detected and/or eliminated. Nonetheless, a justifiable concern is that forensic samples are relatively rarely pure (with the exception of blood collected by venipuncture).

There are many potential sources of contaminating DNA, including DNA contributed by the victim, bystanders, the analyst, or even other organisms. There is also the concern that previously amplified DNA will contaminate the test DNA sample as it is being processed within the lab.¹³⁰

Contaminating DNA From Species Other Than Humans. The DQ α test system is designed with very specific primers and probes. In numerous tests, it was established that only primate DNA is amplified in this test system.¹³¹ DNA from dogs, cats, bacteria, viruses and other organisms will not be amplified nor even detected.¹³² Thus, unless a chimpanzee or gorilla is involved in a crime scene,

some situations, transport of blood is impractical. In the veterinary setting, hair samples may be much easier to get than blood. This could be very important in endangered species programs where the risk of stress and/or anesthesia used during blood collection may be too great. Collection of hair samples makes it much easier to get the information desired, but with the least impact upon the animal. Also, if the animal is dead, blood may not be available, making hair the sample of choice.

See also, Rieko Uchihashi et al., *Deoxyribonucleic Acid (DNA) Typing of Human Leukocyte Antigen (HLA)-DQA1 From Single Hairs in Japanese*, 37 J. FORENSIC SCI. 853 (1992).

127. Higuchi et al., *supra* note 126, at 545.

128. RICHARD E. BISBING, *THE FORENSIC IDENTIFICATION AND ASSOCIATION OF HUMAN HAIR* 185 (Richard Saferstein ed., 1982).

129. See, Russell Higuchi & Edward T. Blake, *Applications of the Polymerase Chain Reaction in Forensic Science*, BANBURY REP. 32: DNA TECH. AND FORENSIC SCI. 265, 273 (1990).

130. S. Kwok & R. Higuchi, *Avoiding False Positives with PCR*, 339 NATURE 237, 237 (1989); Eden Fisher & David R. Lincoln, 7 RECOMBINANT DNA TECH. BULL. 1 (1984); J. Fenton Williams, 7 BIOTECHNIQUES 762, 767 (1989); and Richard A. Gibbs & Jeffrey S. Chamberlain, *The Polymerase Chain Reaction: A Meeting Report*, 3 GENES & DEVELOPMENT 1095, 1097 (1989).

131. USER GUIDE, *supra* note 82, at 6-27; Cetus Corporation, *Background Information: Polymerase Chain Reaction—PCR Technology*, Nov. 1987; and Cetus Corporation, *Forensic Analysis By the Polymerase Chain Reaction (PCR)*, CETUS BACKGROUNDER, Feb. 1990.

132. USER GUIDE, *supra* note 82, at 6-27. Also, while amplified DNA from chimps and gorillas will hybridize to the probes, amplified DNA from more distantly related primates does not hybridize. See also Gyllenstein & Erlich, *supra* note 71.

there is no danger that non-human DNA will be amplified or detected by this test.

Contaminating DNA From "Extraneous" Humans. One concern voiced by some commentators is that, unlike the "pristine" medical setting in which pure samples are supposedly ensured, forensic samples often contain DNA from more than one person.¹³³

However, while mixed samples are probably the norm for forensic samples, anyone who has worked in a hospital can attest that the medical environment is anything but pristine, and pure samples are sometimes impossible to obtain. A prime example of this is amniocentesis, in which samples contain cells contributed by the mother as well as by the fetus. Another example involves the detection of cancerous¹³⁴ or HIV-infected cells,¹³⁵ where the entire point of the test is to identify the few malignant or infected cells hidden within a large population of normal cells. A third example is the detection of HIV-1 in discarded needles.¹³⁶ It would seem very difficult to argue that these three situations reflect the "large," and "clean" samples many commentators associate with the use of PCR and other DNA techniques in medical and research labs.¹³⁷ Contrary to the depiction by one commentator that "scientists analyze fresh, hygienic and relatively unlimited amounts of DNA,"¹³⁸ clinical and research laboratories often must work with small quantities of contaminated samples which are not necessarily "fresh" nor

133. Peter J. Neufeld & Neville Colman, *When Science Takes the Witness Stand*, SCI. AM. May 1990, at 46; Simon Ford & William C. Thompson, *A Question of Identity*, 4 CAL. DEFENDER No. 3 42, 43 (undated); Anthony Pearsall, Comment, *DNA Printing: The Unexamined "Witness" in Criminal Trials*, 77 CAL. L. REV. 665 (1989); Stephen C. Petrovich, *DNA Typing: A Rush to Judgment*, 24 GA. L. REV. 669 (1990); William C. Thompson & Simon Ford, *DNA Typing: Acceptance and Weight of the New Genetic Identification Tests*, 75 VA. L. REV. 45 (1989) [hereinafter *DNA Typing*]; William C. Thompson & Simon Ford, *Is DNA Fingerprinting Ready for Trial? (An Update)*, 4 CAL. DEFENDER No. 3, 36 (undated); C. Thomas Blair, Comment, *Spencer v. Commonwealth and Recent Developments in the Admissibility of DNA Fingerprint Evidence*, 76 VA. L. REV. 853 (1990); Hoeffel, *supra* note 1; Michael Damore, *What Every Criminal Lawyer Should Know*, 27 CRIM. L. BULL. 114, 116-117 (1991).

134. This includes detection of human papillomavirus infection, a risk factor for development of squamous and glandular neoplasia of the genital tract. Marion T. Cornelissen et al., *Localization of Human Papillomavirus Type 16 DNA Using the Polymerase Chain Reaction in the Cervix Uteri of Women with Intraepithelial Neoplasia*, 70 J. GEN. VIROLOGY 2555 (1989).

135. Winand Lange et al., *Detection by Enzymatic Amplification of ber-abl mRNA in Peripheral Blood and Bone Marrow Cells of Patients with Chronic Myelogenous Leukemia*, 73 BLOOD 1735 (1989); *PCR Profiles: Polymerase Chain Reaction in Situ*, AMPLIFICATIONS Mar. 1990 at 20. See also, Ou, *supra* note 58.

136. Stephen Raffanti et al., *Determination of HIV-1 Status of Discarded Sharps: Polymerase Chain Reaction Using Minute Quantities of Blood*, 264 JAMA 2501 (1990).

137. Thompson & Ford, *supra* note 133, at 36, 38; Pearsall, *supra* note 133, at 671.

138. Pearsall, *supra* note 133, at 671.

"hygienic." It is also very difficult to argue that some settings in which PCR has found widespread use provide large and clean samples (e.g., molecular anthropology and paleontology).

If medical science can cope with potentially significant "contamination" problems, it is reasonable to believe that contamination problems may be just as effectively dealt with in the forensic setting. Indeed, this has been recently and conclusively established in two cases, one involving the rather gruesome disappearance of a child,¹³⁹ and the other involving identification of a murder victim from 8-year old skeletal remains.¹⁴⁰ The tidbits of human tissue mixed among corn silage and the skeletal remains exposed to the elements for eight years were amenable to the PCR analysis which answered the questions asked in these two cases. Thus, it is highly likely that PCR will continue to be used in similar cases where vanishingly small quantities of sample are available, as well as in cases where the species of the sample source must be determined.¹⁴¹ PCR may also prove useful in cases in which there may be a question of whether the blood present in an evidence sample was contributed by a human or some other animal.

The FBI conducted an extensive validation study on the effects of induced contamination and sample handling on the ability to perform PCR analysis.¹⁴² The study included dried or moist stains put together, blood mixed with perspiration stains on a shirt, blood-stains which were physically handled, contaminated by exposure to aerosols created by coughing, mixed with shed scalp tissue, and placed in contact with contaminated scissors, and blood that was

139. The 2-year old daughter of two farm laborers was reported as missing during the corn harvest. Unidentifiable tissues were subsequently found among the silage. Samples from the parents and the recovered tissues were tested with both RFLP and the DQ α test system. The DNA results indicated that the tissue recovered from the silage was human and confirmed the probable parentage of the two farm workers. P. Mulhare et al., *An Unusual Case Using DNA Polymorphisms to Determine Parentage of Human Remains*, 12 AM. J. FORENSIC MED. PATHOLOGY 157 (1991).

140. Enka Hagelberg et al., *Identification of the Skeletal Remains of a Murder Victim by DNA Analysis*, 352 NATURE 427 (1991).

141. For example, this could be of great importance in the prosecution of wildlife poachers and importers of endangered species. PCR methods (not HLA DQ α) may be developed to identify which species or subspecies a particular confiscated steak, pelt or mounted trophy belongs. For a discussion of how RFLP is already in use for such purposes, see KIRBY, *supra* note 11, at 233-259. For a brief description of the laboratory most likely to use DNA typing in such circumstances, the National Fish and Wildlife Forensics Laboratory in Ashland, Oregon, see Thomas Brom, *All God's Creatures*, CAL. L., Dec. 1991, at 44-45. A recent article describes the development of probes suitable for use in wildlife forensic science. R.S. Blackett & P. Keim, *Big Game Species Identification by Deoxyribonucleic Probes*, J. FORENSIC SCI. 590 (1992).

142. C.T. Comey & B. Budowle, *supra* note 43.

mixed with other substances such as saliva.¹⁴³ No detectable contamination was found to be introduced by handling, coughing, or the presence of perspiration. Likewise, the two moist stains placed in contact with each other and allowed to dry did not cross-contaminate. However, the mixture of saliva and blood equal amounts appeared to result in a combined HLA-DQ α phenotype; the salivary phenotype appeared to be stronger, probably due to the presence of a large number of epithelial cells.¹⁴⁴

3. Small Number of Forensic Laboratories Using the Test

The small number of forensics laboratories using the test has been a factor for some courts which have excluded PCR evidence.¹⁴⁵ As of March 1991, Cetus reported that over 30 forensic labs were performing DQ α typing.¹⁴⁶ Given the capital outlay required to begin PCR analysis, it is not too surprising that more labs have not started using the technology.¹⁴⁷ In addition, there are costs of training personnel in the proper use of the methods.¹⁴⁸ Sending samples to an outside laboratory is also expensive.¹⁴⁹ Although there are probably many labs who would like to have the capability of using PCR, most of them are unlikely to have the necessary resources available in these lean economic times.¹⁵⁰

In view of the advantages presented by PCR as compared with

143. *Id.*

144. *Id.*

145. *People v. Mack*, No. 861116 (Sacramento Super. Ct. 1991).

146. *Cetus Corporation, Attorney/Investigator Slide Presentation of Forensic DNA Analysis Methods* (unpublished manuscript) [hereinafter Slide Presentation]. In comparison, over 50 forensic labs were "capable" of performing RFLP as of the same date. *Id.*

147. In March 1991, Cetus estimated the total purchase price for all the new capital equipment necessary for PCR analysis to be \$15,000 to \$20,000 for a typical crime lab. However, this is comparatively inexpensive, as RFLP capital equipment costs are estimated at approximately \$150,000 to 200,000. *Id.*

148. In 1991, the cost of a one week training course at Cetus was \$1000. *Id.*

149. In June 1989, DNA testing ranged from \$325/sample at Lifecodes to \$490/sample at Cellmark to \$1500/case at Forensic Science Associates. The expert witness fees (daily rate plus expenses) ranged from \$1,000/day for a Ph.D. or \$750/day for a non-Ph.D. from Cellmark, \$100-\$125/hour for Forensic Science Associates and \$750/day for Lifecodes. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, *GENETIC WITNESS: FORENSIC USES OF DNA TESTS* 25 (1990) [hereinafter *GENETIC WITNESS*].

150. The FBI's report on forensic DNA testing indicates that many labs would be interested in conducting DNA analysis, but lack of necessary personnel, insufficient space or equipment, insufficient budget resources, and insufficient caseload or local demand for DNA testing fail to justify establishing a DNA laboratory. The lack of or difficulty in obtaining a Nuclear Regulatory Commission (NRC) license for handling radioactive materials, the length of time required to become operational and the unavailability of DNA testing training

RFLP, it would be very useful if this analysis was available in every crime lab. Most cases do not require the sophisticated techniques, sometimes difficult interpretations and astronomical numbers generated by RFLP. In most cases, it would seem likely that PCR in combination with other serological markers would provide a quick, relatively inexpensive and very reliable yes/no (inclusion/exclusion) answer.¹⁵¹

4. Interpretation Problems

Some witnesses have testified to discrepancies in the reading of the dot blots. However, these concerns have largely been negated by the inclusion of a "control" dot on the probe strips. This is because in order for the test to be deemed "readable," the intensity of color at a test dot must be at least as intense as that of the "All Control."¹⁵² Thus, if the "all control" (C) dot is more intense than the other dot, it is an indication that the results need careful analysis.

Sexual Assault Evidence Samples. In forensic DNA PCR analysis, sexual assault evidence samples are often involved. Usually, these are the archetypal mixed samples, typically containing a sperm cell component contributed by the male rapist and vaginal epithelial cells contributed by the female victim. Techniques such as "differential lysis" have been developed, which allow good separation between the sperm and epithelial cell fractions.¹⁵³

Differential lysis takes advantage of the physical and biochemical characteristics and differences between the relatively resistant sperm cells and the relatively fragile epithelial cells. Epithelial cells will lyse (burst) under conditions which are much less harsh than those required to lyse sperm. Thus, by lysing the epithelial cells and centrifuging the sample to physically separate the sperm from the epithelial DNA now present in suspension on the top of the sperm

were other concerns. Jay V. Miller, *The Outlook for Forensic DNA Testing in the United States*, 17 CRIME LABORATORY DIG. 1 (Supp. 1) (1990).

151. PCR analysis can be completed within a few days, while RFLP often requires weeks of work. Slide Presentation, *supra* note 146, at 15.

152. The "C" dot is the weakest on the strip. If it is absent, an accurate determination of the type cannot be made. This is because there may be other probe signals below the threshold of detection. The "C" dot provides assurance that the appropriate typing and sub-typing dots should be clearly visible. If visible dots with signal intensities less than the "C" dot are present, this is an indicator of possible procedural error, mixed samples, DNA contamination or the presence of DX α , DQ α type 1.3,4, or subtypes of the DQA 4 allele. USER GUIDE, *supra* note 82, at 4-1. The package insert also contains a useful section on troubleshooting. *Id.* at 29-34.

153. Giusti et al., *supra* note 46; and USER GUIDE, *supra* note 82, at 3.18 to 3.19.

fraction, the DNA from the victim may be harvested from the evidence sample. In subsequent steps, the sperm are lysed and the rapist's DNA is harvested.

In a typical sexual assault case, many samples are tested simultaneously. "Mixed" evidence samples, such as those from vaginal swabs or semen stains on the victim's clothes, are tested along with "pure" DNA collected from both the suspect and the victim, and the sperm cell and epithelial cell fractions are isolated from a portion of the "mixed" evidence sample. By testing all of the various combinations of the above samples, along with samples from any other person who may have contributed DNA to the evidence (e.g., sperm contributed by the victim's boyfriend if he had intercourse with the victim prior to the sexual assault) will allow determination of the allelic composition of each sample. Because each person only has two alleles, a maximum of two alleles should be identified in each sample. However, if the sample is mixed, it is very likely that three or more alleles will be detected. Of course, if the two people share the same DQ α type, there will still only be two alleles identified, even if the sample is "mixed." However, they will also be found to have the same type in their "pure" samples. Thus, there are internal controls within the test methodology which help ensure that the results obtained by the laboratory are correct and reliable. Nonetheless, these results simply mean that the suspect can neither be included nor excluded from the pool of potential suspects based on PCR DQ α typing. Other means of identification and other types of evidence will probably be required for conviction.¹⁵⁴

Other Sample Types. Mixed samples may also be found in bloodstains and other biological evidence. In this case, it becomes even more important to test "pure" samples from both the victim and the suspect. Differential lysis will not work in this situation, as there is no significant difference in the resistance to harsh environmental conditions of blood cells obtained from different people.

While mixed samples are very common, there are numerous legal circumstances in which "pure" DNA samples are available. These include paternity determinations¹⁵⁵ and cases involving the identification of murder victims.¹⁵⁶ The expense of DNA testing is

154. USER GUIDE, *supra* note 82, at 4-6 to 4-8.

155. See B.P. Ludes et al., *Parentage Determination on Aborted Fetal Material Through Deoxyribonucleic Acid (DNA) Profiling*, 36 J. FORENSIC SCI. 1219 (1991).

156. Akane et al., *supra* note 57; Yvonne Baskin, *DNA Unlimited*, DISCOVER, July 1990, at 77; Cetus Corporation, *supra* note 57; Jeremy Cherfas, *Genes Unlimited*, NEW SCIENTIST, April 1990, at 29; *Forensics Experts Tackle Task of Identifying Thousands of 'Disappeared' Victims*, 261 JAMA 1388 (1989); Hagelberg et al., *supra* note 140; Lawrence Kobilinsky &

particularly justified when corroborating evidence in difficult cases is needed to help convince the jury of the suspect's guilt or innocence. However, it is unlikely to supplant the other major identification test systems such as fingerprint analysis, red cell typing (e.g., ABO), and other methods commonly used to identify a suspect as the perpetrator of a crime. It is most probable that PCR will be used as an adjunct test in combination with other evidence and analyses to help bolster a case and ensure either a conviction or an acquittal.

F. Laboratory Design and Test Protocols

This section highlights additional aspects of DNA testing which attorneys must keep in mind. While attorneys involved in DNA cases must understand the technology to a certain extent, they also must have an awareness of laboratory set-up and procedures. It is important for the legal community to realize that laboratory design and test protocols are potentially significant aspects of the tests which may need to be addressed in court.

It is highly advisable for attorneys to be extremely familiar with the laboratory and the person who conducted the tests on the evidence. Thus, if the opponent to the test procedure raises issues regarding contamination, the well-prepared proponent of the evidence should be able to counter the arguments with specific descriptions, photographs or other documentation of the care and diligence with which samples are handled and tested in the laboratory. On the other side of the fence, if the opponent of the evidence is aware of sloppy technique, the lack of controls and/or unsuitable laboratory design which could foreseeably lead to contamination, this would be an important argument against the evidence.

Because laboratory design and test protocols play potentially very significant roles in the success of DNA testing conducted in a particular facility, the laboratory and test protocols should be established with the potential contamination problems in mind. Envi-

Louis Levine, *Recent Application of DNA Analysis to Issues of Paternity*, 33 J. FORENSIC SCI. 1107 (1988); Henry C. Lee et al., *Genetic Markers in Human Bone: I. Deoxyribonucleic Acid (DNA) Analysis*, 36 J. FORENSIC SCI. 320 (1991); Henry C. Lee et al., *DNA Analysis in Human Bone and Other Specimens of Forensic Interest: PCR Typing and Testing*, 31 J. FORENSIC SCI. SOC'Y 213 (1991); Roger Lewin, *A Matter of Maternity*, 233 SCI. 522 (1986); B.P. Ludes et al., *Parentage Determination on Aborted Fetal Material Through Deoxyribonucleic Acid (DNA) Profiling*, 36 J. FORENSIC SCI. 1219 (1991); J. Madeleine Nash, *Ultimate Gene Machine*, TIME, August 12, 1991, at 54; Schwartz et al., *supra* note 44; and Darryl Shibata et al., *Fixed Human Tissues: A Resource for the Identification of Individuals*, 36 J. FORENSIC SCI. 1204 (1991).

ronmental contamination from within the laboratory may result from the introduction of DNA from the analyst, another unamplified sample or a previously amplified sample. Although these present important considerations, good laboratory practice will overcome them.¹⁵⁷ Gloves should be worn at all times, masks should be worn by laboratorians working with samples, aerosols should be minimized, and sample tubes should be tightly closed when not in use.¹⁵⁸

To prevent the transfer of DNA from one sample to another, extra precautions should be taken during the DNA extraction and PCR setup steps. Simple precautions such as using a fresh pipette tip for each sample, carefully opening reaction tubes, and keeping the tubes closed when they are not being used will prevent this type of contamination.¹⁵⁹ The DNA extraction and PCR setup of evidence samples should be done at a separate time from the DNA extraction and PCR setup of reference samples to prevent cross-contamination.¹⁶⁰ It is also recommended that DNA extraction of samples containing high levels of DNA (e.g., whole blood) be conducted separately from samples with low DNA levels (e.g., single hairs, small bloodstains, etc.).¹⁶¹

Laboratory design features and strict adherence to recommended methods will avoid the problem of "carry-over" (contamination of a sample with amplified DNA from a previous PCR reaction). Carryover contamination is a major concern because amplification product is an ideal substrate for subsequent amplifications.

A single PCR reaction produces an enormous number of copies (as many as 10^{13}) that can potentially contaminate samples yet to be amplified. Since the number of copies of amplified DNA in a completed PCR reaction is so high, inadvertent transfer of even a minute volume to a yet to be amplified sample by splashing or aerosol may result in the amplification and typing of the "contaminating" DQ α sequence. For example, if reusing a pipette tip transfers 0.1 μ L, this can be as many as 10^{10} copies of amplifiable sequence. By comparison, a microgram of human genomic DNA contains only about 10^5 copies of a single-copy gene like

157. "Tidiness and adherence to a strict set of protocols can avoid disaster." B. Furrer et al., *Improving PCR Efficiency*, 346 NATURE 324 (1990); see also, S. Kwok & R. Higuchi, *Avoiding False Positives With PCR*, 339 NATURE 237 (1989).

158. USER GUIDE, *supra* note 82, at 2-1. Also, as a general rule, it is good practice to wear lab coats to protect street clothes from splashed chemicals.

159. *Id.*

160. *Id.* at 2-3.

161. *Id.*

DQα.¹⁶²

Thus, nothing should move "upstream" in the flow of analysis. The laboratory should be organized into three designated work areas so that the area in which amplified DNA is handled is physically isolated from the DNA extraction and PCR setup work areas (e.g., separate rooms). While they may be located in the same room, the evidence handling and DNA extraction area should be a separate, distinct work area from the PCR set up area.¹⁶³ Microscopy, photography and any other evidence handling activities should be conducted in the DNA extraction work area.¹⁶⁴ If the work area where amplified DNA is handled is a separate but contiguous room, the laboratory design should be such that air flows toward the amplified DNA area. Dedicated equipment should be clearly labelled for use in each specific work area and not be used elsewhere.

Various researchers concerned with the problems of carryover contamination and the expenses involved in completely segregated laboratory designs have developed internal methods within the PCR reaction tubes to control such contamination.¹⁶⁵ In these methods, amplified DNA is rendered incapable of re-amplification in a subsequent test should it contaminate another sample. While these methods provide additional protection against contamination, they still must be used in conjunction with good laboratory technique.

Regardless of the contamination prevention methods used, no equipment, large or small, expendable or not, should be allowed to move from one designated section of the lab to another.¹⁶⁶ The

162. *Id.* at 2-1.

163. USER GUIDE, *supra* note 82, at 2-2.

164. For detailed special precaution guidelines regarding this area, see *Id.* at 2-3 to 2-4.

165. Stephen Isaacs et al., *Post-PCR Sterilization: Development and Application to an HIV-1 Diagnostic Assay*, 19 NUCLEIC ACIDS RES. 109 (1991); George D. Cimino et al., *Post-PCR Sterilization: A Method to Control Carryover Contamination for the Polymerase Chain Reaction*, 19 NUCLEIC ACIDS RES. 99 (1991); Chin-Yih Ou et al., *Use of UV Irradiation to Reduce False Positivity in Polymerase Chain Reaction*, BIOTECHNIQUES 442 (1991); Yu Sheng Zhu et al., *The Use of Exonuclease III for Polymerase Chain Reaction Sterilization*, 19 NUCLEIC ACIDS RES. 2511 (1991); Mary C. Longo, *Use of Uracil DNA Glycosylase to Control Carry-over Contamination in Polymerase Chain Reactions*, GENE 125 (1990); Gobinda Sarkar & Steve Sommer, *Shedding Light on PCR Contamination*, 7 NATURE 343 (1990); Gobinda Sarkar & Steve Sommer, *More Light on PCR Contamination*, 347 NATURE 340 (1990); Y. Jinno et al., *Use of Psoralen as Extinguisher of Contaminated DNA in PCR*, 18 NUCLEIC ACIDS RES. 6739 (1990); and PERKIN-ELMER CETUS, GENEAMP PCR CARRY-OVER PREVENTION KIT, PART NO. N808-0068 PRODUCT LITERATURE (undated).

166. For example, the thermal cycler should not be placed in the area in which samples are prepared.

work flow should always be directed one way. This represents significant protection for the incoming samples as they are processed. As the concerns are no less acute in the forensic setting than they are in the medical and diagnostic arena, preventing carry-over contamination by previously amplified samples through sectioning of the work area, and preventing the upstream movement of samples, equipment and supplies represents good laboratory technique which should be appreciated by everyone who works with PCR. Prior to sending samples to a lab, the attorney would do well to visit the lab and determine whether these precautions are in place.

ADMISSIBILITY AND OTHER ISSUES INVOLVING DNA ANALYSIS IN CRIMINAL TRIALS

With the increasing acceptance of DNA tests in courts throughout the United States, it appears that the admissibility questions regarding these testing methods will eventually be moot. However, the battles are not yet over. PCR cases have been held in Pennsylvania, Kansas, Texas, California, Florida, Virginia, New York, Colorado, Ohio, and Oregon.¹⁶⁷ Overall, as of October, 1991, PCR-based DQ α typing methods were used in biological evidence analysis in over 250 cases.¹⁶⁸ PCR has also been admitted in Italy.¹⁶⁹ The evidence has been excluded in only a few cases.¹⁷⁰ However, the skirmishes are not likely to be over permanently until more appellate level or higher courts have heard PCR cases.

Controversy has long surrounded the admissibility of scientific techniques, especially in the criminal trial setting. Since the 1923 decision in *United States v. Frye*,¹⁷¹ new scientific evidence has been scrutinized by various legal tests throughout the different jurisdictions within the United States.

167. Forensic Science Associates, PCR DNA COURT CASES, HLA DQ α FORENSIC DNA AMPLIFICATION AND TYPING INFORMATIONAL HANDOUT (3/29/91). In one of the latest cases, *People v. Groves*, No. 90CA1049, 1992 Colo. App. LEXIS 369 (Colo. Ct. App. October 8, 1992), the court ruled that the erroneous inclusion of PCR test results related solely to transactional evidence was harmless error even though the trial court did not conduct a preliminary *Frye* test on the PCR evidence.

168. Edward Blake et al., *Polymerase Chain Reaction (PCR) Amplification and Human Leukocyte Antigen (HLA)-DQ α Oligonucleotide Typing on Biological Evidence Samples: Casework Experience*, 37 J. FORENSIC SCI. 700 (1992).

169. See Bruno Dallapiccola et al., *PCR DNA Typing for Forensics*, 354 NATURE 179 (1991). A subsequent paper challenged the methods used in the PCR tests admitted in the case referred to in the Dallapiccola paper. Angelo Fiori & Vincenzo L. Pascali, *Forensic Use of PCR in Italy*, 356 NATURE 471 (1992).

170. *People v. Martinez*, No. C 82183 (Los Angeles Super. Ct. 1989); and *People v. Mack*, No. 861116 (Sacramento Super. Ct. 1990).

171. 293 F. 1013 (D.C. Cir. 1923).

Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.¹⁷²

As with many other scientific methods, there has been a long history of attacks on the scientific analysis of blood and other body fluids. As recently as 1988, there were court challenges to the reliability of ABO typing of blood and other stain evidence.¹⁷³

In the case of DNA analyses, most of the arguments go back to the traditional claim that forensic evidence is different from clinical samples obtained in the "pristine" medical setting. These same arguments occurred in the 1970s-1980s regarding electrophoretic typing of proteins such as PGM in bloodstains and other bodily fluid evidence.¹⁷⁴ It was not until the relatively recent case of *People v. Reilly*,¹⁷⁵ that the electrophoresis debate was settled for good in California.

The DNA debate is still very active, as evidenced by the approximately twenty appellate and state supreme court decisions discussing the admissibility of DNA typing.¹⁷⁶

172. *Id.* at 1014.

173. C. Holden, *Science in Court*, 243 SCI. 1658 (1987); and W.F. Rylaarsdam, *Farewell to Hired Guns, Judges Should Pick Their Own Experts to Testify on Technical Issues*, S.F. DAILY J., August 26, 1992, at 4. See also, Sheila Jasanoff, *Science on the Witness Stand*, ISSUES SCI. TECHN., Fall 1989, at 80.

174. David D. Dixon, *The Admissibility of Electrophoretic Methods of Genetic Marker Bloodstain Typing Under the Frye Standard*, 11 OKLA. CITY U. L. REV. 773 (1986); R.E. GAENSSLEN, SOURCEBOOK IN FORENSIC SEROLOGY, IMMUNOLOGY, AND BIOCHEMISTRY (1983); R.E. GAENSSLEN (ED.), SOURCEBOOK IN FORENSIC SEROLOGY, IMMUNOLOGY, AND BIOCHEMISTRY UNIT IX: TRANSLATIONS OF SELECTED CONTRIBUTIONS THE ORIGINAL LITERATURE OF MEDICOLEGAL EXAMINATIONS OF BLOOD AND BODY FLUIDS (1983); Joseph R. Melvin et al., *Paternity Testing*, in 2 FORENSIC SCIENCE HANDBOOK 273 (Richard Saferstein ed., 1988); F. Samuel Baechtel, *The Identification and Individualization of Semen Stains*, in 2 FORENSIC SCIENCE HANDBOOK 348 (Richard Saferstein ed., 1988); Henry C. Lee, *Identification and Grouping of Bloodstains*, in FORENSIC SCIENCE HANDBOOK 267 (Richard Saferstein ed., 1988); and Sensabaugh, *supra* note 114.

175. 242 Cal. Rptr. 496 (Cal. Ct. App. 1987).

176. George W. Clarke, *supra* note 76, at 5,7. For a sample of a *Kelly-Frye* motion in opposition to the introduction of RFLP evidence, see Walter F. Krstulja, *Sample Kelly-Frye Motion Opposing the Introduction of DNA (RFLP) Evidence*, 5 CAL. DEFENDER, No. 1, 1992, at 40.

A. California's *Kelly-Frye* Test

In assessing whether scientific evidence should be admitted, California uses the test set forth in *People v. Kelly*,¹⁷⁷ a case which expands the basic legal prerequisites for admissibility previously established by *Frye*.

[The] admissibility of expert testimony based upon the application of a new scientific technique traditionally involves a two-step process: (1) the *reliability of the method* must be established, usually by expert testimony, and (2) the witness furnishing such testimony must be properly qualified as *an expert to give an opinion* on the subject. Additionally, the proponent of the evidence must demonstrate that correct scientific procedures were done in the particular case.¹⁷⁸

The function of the *Kelly-Frye* rule is to safeguard against the presentation of either unfounded or prematurely developed scientific methods, or unfounded evidence to juries.¹⁷⁹ The reasoning is that "[l]ay jurors tend to give considerable weight to 'scientific' evidence when presented by 'experts' with impressive credentials."¹⁸⁰

Kelly-Frye hearings are preliminary hearings in which the judge determines whether or not to permit particular scientific evidence to be presented to the jury during trial. In a typical *Kelly-Frye* hearing, both the proponent and the opponent of the scientific technique bring in a parade of scientific experts and present their best arguments for or against the admissibility of the particular scientific evidence involved. Thus, the proponent's witnesses will testify to the usefulness, reliability and overwhelming acceptance of the technology within the appropriate scientific community, while the opponent's witnesses will testify to its absolute worthlessness.

It is important to remember that the issue to be decided in a *Kelly-Frye* hearing is the admissibility, not the weight of the evidence.¹⁸¹ In California, the decisions in *People v. Smith*¹⁸² and *People v. Farmer*¹⁸³ have more clearly defined the narrow scope of the legal admissibility inquiry. As stated in *Smith*, "the *Frye* test dictates that *criticism of the specific methodology employed goes to the*

177. 549 P.2d 1240 (Cal. 1976).

178. *Id.* at 1244 (citations omitted)(emphasis in original); *See also*, *People v. Shirley*, 641 P.2d 775, 795 (Cal. 1982); and *People v. Brown*, 709 P.2d 440, 447-448 (Cal. 1985).

179. People's Points and Authorities Defining the Parameters of the *Kelly-Frye* Hearing at 2, *People v. Lewis*, No. C-27037 (San Mateo Super. Ct. Oct. 15, 1991).

180. *Kelly*, 549 P.2d at 1245 (1976).

181. *People v. Marx*, 126 Cal. Rptr. 350, 356 (Cal. Ct. App. 1975).

182. 263 Cal. Rptr. 678 (Cal. Ct. App. 1989).

183. 765 P.2d 940 (Cal. 1989).

credibility of the testimony, not admissibility."¹⁸⁴

As there is no requirement that the court must understand the technology in question, the judge's role in *Kelly-Frye* is relatively limited. In a case involving hypnosis, the California Supreme Court stated, "our duty is not to decide whether hypnotically induced recall of witnesses is reliable as a matter of 'scientific fact,' but simply whether it is generally accepted as such by the relevant scientific community."¹⁸⁵ Nonetheless, because most people probably prefer to know what is going on around them, it would be advisable to present the evidence in such a way that the judge is able to grasp the concepts and understand the technology and vocabulary, at least on a rudimentary level.

Also importantly, there is no requirement for absolute unanimity of views within the scientific community prior to the determination that a new scientific method is reliable.

The *Frye* test does not demand the impossible—proof of an absolute unanimity of views in the scientific community before a new technique will be deemed reliable; any such unanimity would be highly unusual. . . . Rather, *the test is met if the use of the technique is supported by a clear majority of the members of that community.*¹⁸⁶

Kelly/Frye does not demand judicial absorption of all the relevant literature, nor does it require a decision once and for all whether a particular kind of scientific evidence is reliable. The court need only conduct a 'fair overview' of the subject, sufficient to disclose whether 'scientists significant either in number or expertise publicly oppose [a technique] as unreliable' [citation].¹⁸⁷

Quite simply, the only determination to be made during a *Kelly-Frye* hearing is whether or not the scientific technology is generally regarded as reliable within the relevant scientific community. This itself has fueled some debate concerning the scope of the relevant scientific community and the degree of acceptance which can be considered "general." In terms of the "relevant scientific community," it appears that most courts are willing to adopt a broad view with regard to PCR testing.¹⁸⁸

184. *Smith*, 263 Cal. Rptr. at 682-83 n.4 (citing *State v. Adams*, 418 N.W.2d 618 (S.D. 1988))(emphasis in original).

185. *People v. Shirley*, 641 P.2d 775, 797 (Cal. 1982).

186. *People v. Reilly*, 242 Cal. Rptr. 496, 509 (Cal. Ct. App. 1987)(quoting *People v. Guerra*, 690 P.2d 635, 656 (Cal. 1984))(emphasis added).

187. *Reilly*, 242 Cal. Rptr. at 509 (quoting *People v. Brown*, 709 P.2d 440, 450 (Cal. 1985)).

188. The judges in some cases have indicated that the relevant scientific community is

At the hearing, the proponent of the evidence has the burden of bringing in suitable expert witnesses willing to testify to the acceptance of the technology in the scientific community. In order to testify, the witness(es) must be properly qualified by the court as expert(s) in the field. With the help of the attorney, the proponent's expert witnesses must establish, by a preponderance of the evidence, that the method is reliable and accepted within the scientific community. Thus, the proponent of the evidence has the burden of making the necessary showing of compliance with *Frye*, (i.e., of demonstrating by means of qualified and disinterested experts that the new technique is generally accepted as reliable in the relevant scientific community).¹⁸⁹

In addition to the reliability of the evidence and the qualification requirements for expert witnesses, there is a "correct procedure" prong in the *Kelly-Frye* standard.¹⁹⁰ Thus, it must be determined that the technique was performed reliably in the case at issue, before the evidence may be presented to the trier of fact.¹⁹¹ If the test procedure was not reliably performed, then the evidence should not be admitted. This requirement highlights the necessity for the attorneys to be familiar with the lab and personnel who conducted the DNA analysis.

In addition to correct laboratory procedures, attorneys must be familiar with the statistical methods used to calculate the probabilities that the person on trial is the one responsible for the crime. This is largely due to the large amount of discussion regarding the admissibility status of statistical evidence.

For example, in *People v. Collins*,¹⁹² the prosecution's use of statistical approximation was criticized on two levels: (1) the prosecution failed to introduce proof of the probability of individual events; and (2) the prosecution failed to present any proof of the mutual independence of those individual frequencies. However, this decision does not stand for the proposition that in the face of

not limited to forensics, but encompasses the entire scientific community which uses PCR. *People v. Moffett*, No. 103094 (San Diego County Super. Ct. May, 1991); *People v. Quintanilla*, No. C-23691 (San Mateo County Super. Ct. Aug. 16, 1991). However, there have been other *Kelly-Frye* hearings in which the PCR evidence was excluded as not being accepted in the relevant scientific community. *People v. Mack*, No. 86116 (Sacramento Super. Ct. Sept. 1990).

189. *Shirley*, 641 P.2d at 796. See also, *Brown*, 709 P.2d at 447-448, and *Kelly*, 549 P.2d at 1244.

190. *Kelly*, 549 P.2d at 1244.

191. *Reilly*, 242 Cal. Rptr. at 513-14; *People v. Dellinger*, 209 Cal. Rptr. 503, 509-10 (Cal. Ct. App. 1984).

192. 438 P.2d 33 (Cal. 1968).

disagreement regarding the quality of proof on either of these points, a trial judge has the authority to preclude their presentation to the jury.

In *People v. Yorba*,¹⁹³ the court followed well established California precedent in finding that statistical estimations based on biological evidence is a weight and not an admissibility issue, particularly when the estimations are based on the application of long-standing scientific principles.¹⁹⁴ It would certainly seem that the Mendelian inheritance exhibited by HLA DQ α would fall into the category of "long-standing scientific principle." Even test procedures which have the potential for statistical estimation, but which yield only equivocal results, have been deemed admissible.¹⁹⁵ The simple fact that a defendant is not excluded by test results has been found relevant for the jury to learn.¹⁹⁶ Thus, the population genetics and frequencies associated with PCR and RFLP should go to the weight of the evidence, not its admissibility.

Nonetheless, many commentators have argued that DNA evidence should be regarded as unreliable unless and until detailed evidence on population structures is available.¹⁹⁷ However, probabilities have been used for many years. Thus, there is no reason to summarily disregard them simply because they are applied to DNA analyses. A "statement of a probability is, by its nature, a statement of partial knowledge, so it is paradoxical to imply that in principle we cannot calculate the probability of an event without further empirical knowledge."¹⁹⁸ Much is already known about the population substructures for various loci, including DQ α . Also, when is enough, enough? When would the opponents to the use of DNA in court cases be satisfied that the population studies were sufficient and the statistical methods appropriate?¹⁹⁹

193. 257 Cal. Rptr. 641 (Cal. Ct. App. 1989).

194. *Id.* at 645-646.

195. In *People v. Cooper*, 809 P.2d 865 (Cal. 1991), two cigarette butts found at a crime scene were analyzed in an attempt to determine whether the defendant might have smoked them.

This endeavor would have been much easier if PCR had been used to analyze saliva on the cigarette butts. M.N. Hochmeister et al., *PCR-Based Typing of DNA Extracted From Cigarette Butts*, 104 INT'L J. L. MED. 229 (1991).

196. *Cooper*, 809 P.2d at 888.

197. See, e.g., R.C. Lewontin & D.L. Hartl, *Population Genetics in Forensic DNA Typing*, 254 SCI. 1745 (1991).

198. John Brookfield, *Law and Probabilities*, 355 NATURE 207 (1992).

199. See D.A. Stoney, *Reporting of Highly Individual Genetic Typing Results: A Practical Approach*, 37 J. FORENSIC SCI. 373 (1992) for a detailed discussion of the interpretation of serologic typing data, population genetics, statistics, and the peculiarities of DNA testing in the forensic arena.

B. *The Bar's Response to DNA Testing*

It is somewhat surprising that defense associations are so adamantly opposed to DNA tests when they can absolutely exclude a person on trial from being the perpetrator of the crime.²⁰⁰ A good example is the first suspect arrested in the *Quintanilla* case, but exonerated based on PCR typing.²⁰¹ Of 250 PCR cases, 70% of the PCR analyses were requested by the prosecution and 30% by the defense.²⁰² In 198 cases, 35% resulted in the exclusion of the suspect and 65% in inclusion; the same percentage of inclusions was obtained for cases done at the request of the prosecution as those done at the request of the defense.²⁰³

The power of exclusion represents much of the benefit provided by PCR. If a suspect is excluded, that's it. If a suspect is included, that's all it means. Other evidence will be needed in order to conclusively establish that the person is indeed the true culprit. The defense should consider the possibility that without DNA evidence, an innocent person may be convicted.

The high rate of exclusions (including inconclusive results) may be due to various factors, including the irrelevance of the evidence to the crime, or, in sexual assault cases, the failure of the rapist to ejaculate, or recent sexual activity of the victim.²⁰⁴ Until additional systems are developed which will enhance the discrimination power of the tests, other testing methods and/or evidence will be required in order to result in conviction. Because DNA testing is so useful to the innocent defendant, one would think that defense attorneys would be more circumspect in their evaluation of the methods. Post-conviction reversals due to PCR test results have been obtained in at least five cases.²⁰⁵ It is rather hypocritical to oppose the admission of DNA tests when the prosecution is the proponent of the evidence, but vigorously work for its admission when

200. Edward T. Blake et al., *Polymerase Chain Reaction (PCR) Amplification and Human Leukocyte Antigen (HLA)-DQA Oligonucleotide Typing on Biological Evidence Samples: Casework Experience*, 37 J. FORENSIC SCI. 700 (1992). See also, Sherman, *supra* note 1.

201. See *supra* note 8.

202. Blake et al., *supra* note 200, at 721.

203. *Id.*

204. *Id.*

205. Telephone Interview with Edward Blake, Forensic Science Associates (Nov. 5 1992). These defendants include Gary Dotson (Illinois), Woodall (West Virginia), Joe Jones (Kansas), Steve Linscott (the "dream slayer") (Illinois), and Cary Cotler (New York).

In the Woodall case, the defendant recently settled with West Virginia for \$1 million, the maximum sum which he could have received had there been a trial. This settlement was apparently arranged by the state in order to avoid revealing the full extent of prosecutorial misconduct which occurred during Mr. Woodall's trial. *Id.*

the defense is the proponent.²⁰⁶ Indeed, this appears to be the case in an on-going attempt by Peter Neufeld, a prominent New York attorney, to reverse the New York conviction of a man serving time for rape.²⁰⁷ Mr. Neufeld has been against the admission of DNA results.²⁰⁸ However, as it now appears that PCR will be able to exonerate a client, he has become a proponent of the test.

To date, there have been no cases in which an innocent defendant has been convicted solely on the basis of DNA analysis. Such a circumstance is likely to never occur. Indeed, in a recent Connecticut case, the jury completely disregarded the exonerating DNA evidence.²⁰⁹ "At times, testing fails to produce results, but it has never created false positives."²¹⁰

One author argues that the rights involved in criminal trials are so overwhelmingly important that such a new technology should not be used.²¹¹ However, these arguments are greatly diminished by the fact that PCR is used in many life and death settings, many of which involve no "suspect."²¹² For example, PCR is used in genetic counselling²¹³ and may contribute to the decision of a couple to terminate a pregnancy should the fetus be severely de-

206. Judge Mudd noted that in different cases, both the prosecution and the defense have opposed PCR. Reporter's transcript, at 1010, *People v. Moffett*, No. 103094 (San Diego Super. Ct. 1991). Judge Mudd views this as indication that PCR is ready for the courtroom; it isn't any different from any other evidence—"if it's for you, you're willing to support it; if it's agin you, you're willing to challenge it." *Id.* at 1010. He found it an interesting and telling factor that in a number of cases, the defense had found it necessary to support PCR. *Id.* at 1010-1011.

207. As relayed by Edward Blake, *supra* note 205. See also, Sherman, *supra* note 1.

208. See Peter J. Neufeld and Neville Colman, *When Science takes the Witness Stand*, SCI. AM. May, 1990, at 46.

209. In March 1990, a six-person jury ignored the exculpating DNA evidence analyzed for the defense by the FBI laboratory and convicted Ricky Hammond of a 1987 kidnapping and rape. See *Connecticut's Doubtful Claim to Fame: DNA Results Rejected by Jury*, SCI. SLEUTHING NEWSL., Winter 1990, at 6; Jack Ewing, *Connecticut Jury Disregards DNA Test*, NAT'L L.J., Apr. 23, 1990, at 9.

In *Moffett*, Judge Mudd noted that, "I don't think trial lawyers give jurors enough credit for being intelligent, because my personal experience with RFLP was that in jury questionnaires they were able to put that particular evidence in the context of the entire trial and give it the weight to which they felt it to be entitled." Kelly/Frye Hearing Transcript at 1014, *People v. Moffett*, CR-103094 (San Diego Super. Ct. 1991).

210. L. Koblinsky, *Recovery and Stability of DNA in Samples of Forensic Science Significance*, 4 FORENSIC SCI. REV. 67, 79 (1992).

211. See Hoeffel, *supra* note 1, at 495.

212. The fact that life and death decisions are being made daily based on PCR made such a significant impression on Judge Mudd, that he commented on Judge Tochtermann's finding that in criminal law, the standard must go beyond that acceptable in the medical, scientific and research communities. Reporter's Transcript at 1007, *People v. Moffett*, No. 103094 (San Diego Super. Ct. 1991).

213. This also includes determining the sex of a fetus. Michal Witt & Robert P. Erick-

formed or genetically "defective." The couple is able to make the tough, yet informed decision concerning whether to terminate the pregnancy or be prepared for a child with special requirements and needs should they choose to continue the pregnancy. The use of PCR in the genetic assessment of fetuses is most certainly of life and death importance and magnitude.

The use of PCR in genetic counselling may impact the choice of prospective parents to even conceive.²¹⁴ If they know that they are extremely likely to have an infant with serious mental and/or physical impairments, a couple may be more likely to adopt a healthy child rather than take the risk of having their own.

With the overwhelming acceptance of PCR in a wide variety of scientific disciplines and its increasing court acceptance, admissibility should soon be an issue of the past. The fight can then be shifted to the weight of the evidence, as it is with most other types of physical evidence presented at trial. Whether the laboratory is reputable, conducts "good" science, and follows established protocols will become the primary focus. If the laboratories conducting the tests meet the strictest of controls, then the evidence should be allowed to speak for itself in either implicating or exonerating the involved person. Expert witnesses should help, rather than hinder the court in understanding the technologies and their limitations.

C. *Expert Witnesses*

In view of its widespread use and overwhelming adoption by a great number of scientists working in numerous disciplines worldwide, it is very difficult to imagine that a molecular biologist with any practical experience would agree to testify that PCR is unreliable and not useful in the appropriate scientific community.²¹⁵ Perhaps the availability of generous expert witness fees and the perceived ego-boost associated with legal recognition as an "expert" has led some scientists, traditionally short of funding for their research projects to make statements in court which are not only misleading, but are actually false.

Great care must be used in the selection of expert witnesses.

son, *A Rapid Method for Detection of Y-Chromosomal DNA From Dried Blood Specimens by the Polymerase Chain Reaction*, 82 HUM. GENETICS 271 (1989).

214. See Scott C. Kogan et al., *An Improved Method for Prenatal Diagnosis of Genetic Diseases By Analysis of Amplified DNA Sequences*, 317 NEW ENG. J. MED. 985 (1987).

215. It is even included as an important part of the most recent genetics textbooks such as SINGER & BERG, *supra* note 9, at 420-25.

One author suggests that qualified experts should exhibit the following:

(1) undergraduate and graduate degrees in the relevant field of expertise, (2) specialized training in the subject area as it relates to forensics, (3) some training in forensics, (4) those professional licenses or certifications universally required by recognized professional groups in the expert's discipline, (5) evidence of experimentation, teaching, publication within the specialty area, or some combination of these, (6) prior disciplinary evidence that is direct and relevant to the issues or issues being considered. Also desirable would be (1) postgraduate (or postdoctoral) training, (2) publications which appear in (reviewed) scientific journals, (3) the development of scientifically acceptable tests or procedures, (4) association with, and leadership in, appropriate scientific societies, and (5) experiences as an expert witness.²¹⁶

Not only must expert witnesses in DNA trials be well-informed and current on the most up-to-date technologies, they should also have practical experience in the methods used to analyze DNA. Those "experts" whose only experience has been gained tangentially or solely through the literature should be viewed with great skepticism.

The Court in *People v. Brown*,²¹⁷ included an additional caveat—that the witness "must also be 'impartial,' that is, not so personally invested in establishing the acceptance of the technique that he might not be objective about disagreements within the relevant scientific community."²¹⁸ Common warning signs that an expert witness is biased include, that he/she (1) is exclusively or almost exclusively, a witness for one side (prosecution or defense), (2) makes statements that he/she "could not be wrong," (3) does not describe the evaluation procedures used in his/her laboratory ("they are classified" or "too complex to understand"), (4) does not bring data, materials or the relevant examination results to the courtroom, and/or (5) makes unwarranted (oftentimes vague) personal attacks on opposing witnesses.²¹⁹

Financial ties and potential biases of any expert witnesses should be disclosed in the trial before the jury, not at the admissibility preliminary hearing stage. The court in *New Jersey v. Wil-*

216. H. Hollien, *Expert Witness: Ethics and Responsibilities*, 35 J. FORENSIC SCI. 1414, 1417 (1990).

217. *People v. Brown*, 709 P.2d 440 (Cal. 1985).

218. *Id.* at 448.

219. Hollien, *supra* note 216, at 1416.

liams²²⁰ stated that, "evidence of the financial rewards that a witness or a corporation with whom he is associated will gain from the use of the new scientific technique will surely be presented to the jury which can determine what weight, if any, to give to the testimony of each expert."²²¹ As the State in the same case contended, "simply because learned experts earn a living with their expertise should not prohibit the admissibility of their opinions."²²² Impartiality concerns have lead to many discussions regarding the testimony of scientists who are very involved in the development and use of new technology, usually within the industry setting. However, there are those within the academic research community who could be viewed as biased one way or another regarding the technology.²²³ Perhaps the ties of all experts should be disclosed to the jury. It is possible that jurors would be shocked at the very generous fees collected by expert witnesses, some of whom seem to be on the "circuit" so to speak, ready and willing to testify for a fee.

One product of the litigation involving DNA typing has been the development of a "cottage industry" or "welfare state" of defense experts (including some attorneys) who travel around the country to testify against the admissibility of DNA testing. For many of these experts, most of their yearly income is derived from in-court testimony.²²⁴ Various authors have expressed concern about the ethics or advocacy displayed by some experts.²²⁵ Perhaps, as some authors have suggested, the court should appoint and pay for expert witnesses, as courts do in other countries.²²⁶

Regardless of their source of payment, it is possible that personal vendettas and a desire to continue a controversy long after it has been resolved (quite possibly in order to continue collecting expert witness fees) will continue to greatly disserve the legal and scientific communities and justice system. Instead of directly addressing the issues in the case, the attorneys, judges and juries are forced to witness the in-fighting and personality conflicts between scientists who sometimes have egos as large as their counterparts in

220. No. 1991 WL 276327, at *7 (N.J. Super. L. Aug. 5, 1991).

221. *Id.*

222. *Id.*

223. Perhaps this is fostered by the highly competitive "publish or perish" mentality within academia. It is undoubtedly a resume enhancer if a scientist can include testifying in court regarding science.

224. Clarke, *supra* note 76, at 27-28.

225. See Hollien, *supra* note 216, at 1415 for a list of references which express this view.

226. Holden, *supra* note 173; and Rylaarsdam, *supra* note 173.

the legal profession.²²⁷

Some scientists, by succumbing to the seductive aspects of testifying in court, have done much to discredit themselves in the eyes of the scientific community at large. Many of these people are simply ill-informed. Although they may not intentionally misrepresent the technology, many are unfamiliar with courtroom procedures, cross-examination, and/or forensics and are made to look like fools through their own testimony.²²⁸

Expert witnesses must be familiar with the techniques used in the particular case in which they are testifying. Many principal researchers within the academic community are professors who do very little actual laboratory research; they are often forced to leave the "bench work" to their post-doctoral fellows, graduate students, undergraduates and technicians. The reality of the academic situation is that professors must devote time to acquiring and administering grants, serving on school committees, advising graduate, undergraduate and potential students, preparing and presenting papers at professional meetings and for publication, participating in school events, as well as teach. It is easy to see why many academics simply do not have the time to conduct much hands-on research themselves. However, it is only through the practical application of these techniques that a scientist will become sufficiently familiar with the methods to testify fairly and accurately.

One embarrassing example is the testimony of Dr. Mary-Claire King, an expert witness who testified in the *People v. Mack*²²⁹ and *People v. Mello*²³⁰ *Kelly-Frye* hearings regarding the AmpliType[®] DQ α test kit. In the *Mack* hearing, Dr. King stated that she was not aware of the results of the test kit blind trials conducted by the California Association of Crime Laboratory Directors and that these results had not been published.²³¹ However, the results of the first round were published in 1988. She also admitted that she was in error when she stated in the *Mello* hearing that Alan Wilson developed PCR technology.²³² Furthermore, she admitted that she had not even read the protocol manual used in conjunction with the

227. See Reporter's Transcript, at 53-54, *People v. Williams*, No. 110047 (San Francisco Super. Ct. 1983); *People v. Brown*, 709 P.2d 440 (Cal. 1985).

228. See, e.g., Reporter's Transcript, at 2248-2252, *People v. Mack*, No. 86116 (Sac. Super. Ct. 1990) [hereinafter, *Mack Transcripts*]. See also, Hollien, *supra* note 216 at 1416-1417.

229. *Mack Transcripts*, *supra* note 228.

230. Reporter's Transcript at 3480, *People v. Mello*, No. 27819 (Riverside Super. Ct. 1989) [hereinafter *Mello Transcripts*].

231. *Mack Transcripts*, *supra* note 228, at 2244-2247.

232. *Mello Transcripts*, *supra* note 230, at 2248-2250.

AmpliType™ DQα test kit (“AmpliType™ User Guide”)²³³, although she testified that she had used the kit. She also testified that she learned about PCR from a paper on the extinct quagga;²³⁴ the “quagga paper” did not even involve the use of PCR.²³⁵

This type of testimony is a shining example of why the academic community is not necessarily the best source for expert witnesses, contrary to the admonitions of Thompson and Ford, two commentators on the use of DNA testing who stated that “[t]o find experts who are “disinterested and impartial,” courts will need to look to the academic community.”²³⁶ It would seem highly probable that an expert in PCR and molecular biology would at least know who originally developed PCR technology. An indignant contingent of scientists very knowledgeable in PCR and molecular biology were sufficiently outraged by the *Mello* admissibility hearings to publish a response to the inaccurate interpretation of the DQα evidence.²³⁷

Justification for the use of academicians as expert witnesses has also included such statements as “[m]ost studies evaluating DNA typing are published by employees of these companies, or university researchers who have a financial relationship with these companies.”²³⁸ However, with the literally thousands of articles on PCR and DNA typing published in the scientific literature, this statement is very difficult to defend.

It is also important for the legal community to realize that one of the major goals of the scientific literature is to present materials, methods and results of particular experiments and investigations, especially in peer-reviewed journals.²³⁹ Scientific articles must be published in a manner such that the experiments may be repeated by others. Results from these repeated experiments are published which either confirm or dispute the procedures and/or results of the original experimenters. It is through this continual interaction between researchers, that scientific principles develop and gain acceptance.

233. *Id.* at 2234-2236, 2281-2282.

234. *Id.* at 3480.

235. Higuchi et al., *supra* note 45.

236. *DNA Typing*, *supra* note 133, at 59. See also, Ricardo Fontg, *supra* note 29, at 530.

237. Henry A. Erlich et al., *Reliability of the HLA-DQα PCR-based Oligonucleotide Typing System*, 35 J. FORENSIC SCI. 1017 (1990).

238. *DNA Typing*, *supra* note 133, at 59.

239. Given the large number of comments and articles in the legal literature which contain erroneous material regarding DNA testing and methods, perhaps the legal profession should consider adopting a peer-review process for law reviews.

It is very unlikely that there is a paper published in the scientific literature which refutes the statements and results of the Higuchi et al. paper,²⁴⁰ called into question by Thompson and Ford²⁴¹ because two of the authors, Higuchi and Erlich are Cetus researchers. Also, not mentioned in the Thompson and Ford article, the other two researchers involved, Celia von Beroldingen and George Sensabaugh, were associated with the University of California, not Cetus. Regardless of their affiliation, just because a scientist works for a particular company does not mean that he or she will be unethical on the witness stand or in the scientific press. To do so is professional suicide. Such persons are eventually discovered and made to pay the price, a good example being the recent investigations into Gallo's laboratories regarding the discovery of HIV.²⁴² Whether a scientist works in the biotechnology industry or at an university, it does not necessarily mean that they leave their ethics at home when they come to testify in court.

D. *The Impact of People v. Castro*²⁴³

Easily the most discussed DNA case, *Castro* has become the signal case used by those opposed to the use of DNA evidence, as it represents the first successful challenge to DNA typing evidence. However, despite the outburst of criticism and dire predictions in the legal and lay literature, *Castro* has not been repeated.

Although others may disagree, and although the case did not even involve a "crime lab" per se, the fiasco of *Castro* has had both positive and negative effects on forensic science. Notwithstanding the outcry regarding the case, the impact of *Castro* in New York courts appears to be minimal, as demonstrated by subsequent cases.²⁴⁴ In many respects, the entire *Castro* incident was really nothing more than a tempest in a teapot.

What has been lost in the excitement generated by the case is the fact that the opinion is merely the trial court's assessment of a legal issue which the prosecution had rendered moot by conceding in its brief that the evidence of a match in DNA patterns was inadmissible. Mr. Castro later pled guilty, thus the soundness of the trial court's legal opinion will never be reviewed on

240. Higuchi et al., *supra* note 126.

241. See *DNA Typing*, *supra* note 133, at 59.

242. Malcolm Gladwell, *At NIH, An Unprecedented Ethics Investigation: New Questions Involving Scientist Robert Gallo and Discovery of HIV Being Probed*, WASH. POST, Aug. 17, 1990, at A8.

243. 545 N.Y.S.2d 985 (N.Y. Sup. Ct. 1989).

244. See, e.g., *People v. Shi Fu Huang*, N.Y.S.2d 920 (N.Y. Co. Ct. 1989).

appeal.²⁴⁵

On the positive side, *Castro* put the laboratories conducting DNA testing on notice that the judicial system is not willing to accept evidence based on sloppy and questionable test methods. While the *Castro* court declined to state that evidence gained through proper procedures would be inadmissible, it did exclude the evidence in this case because Lifecodes, the lab hired to conduct the DNA (RFLP) tests, did not even follow its own guidelines.²⁴⁶ *Castro* also points out some areas in which attorneys can deal with this type of data and possibly find sources of error.²⁴⁷

On the negative side, *Castro* provided much fodder for the opponents of DNA testing who sensationalize the issues and claim to consider DNA testing as either unreliable, unverifiable, too invasive of privacy and/or simply too difficult and complex to understand.²⁴⁸

One bit of science that the *Castro* court seized upon was the "mixing" experiment. While in its judicial activism mode, the court made several suggestions to the scientific community regarding certain procedures, one of which was the mixing experiment proposed by Lander, a prominent population geneticist. Lander insisted that if one mixed a known sample with an unknown sample which was thought to be from the same source prior to performing RFLP, then if the bands moved to the same place on the gel, they could be from the same source.²⁴⁹ While this type of solution to bandshifting in RFLP may be appropriate for paternity cases, it has been shown to be unworkable in forensic cases.²⁵⁰ Unfortunately, the *Castro* court gave great weight to this advice.

Other aspects deserving of mention include: (1) all of the evidence was consumed in the testing; (2) the trial court ruled that the forensic DNA identification test met the *Frye* standard; (3) the court ruled that population frequency data should be related to the

245. Rockne Harmon, *DNA Fingerprinting Critics Titillate Rather Than Inform*, L.A. DAILY J., March 14, 1990, at 6.

246. *Castro*, 545 N.Y.S.2d at 997.

247. Roger Parloff, *How Barry Scheck and Peter Neufeld Tripped Up the DNA Experts*, AM. L., Dec. 1989, at 50.

248. See Petrovich, *supra* note 133; Pearsall, *supra* note 133; Lander, *supra* note 112; Hoeftel, *supra* note 1. These are but a few of the multitude of review articles covering *Castro* and the problems encountered.

249. Lander, *supra* note 112.

250. McNally et al., *Increased Migration Rate Observed in DNA From Evidentiary Material Precludes the Use of Sample Mixing to Resolve Forensic Cases of Identity*, 1 APPLIED THEORETICAL ELECTROPHORESIS 267 (1990), discussed in Amicus Curiae's Brief at 29, *People v. Barney*, No. A048789 (Cal. Ct. App. 1 Dist. 1991).

weight of the evidence, not the admissibility; (4) the court rendered an opinion in spite of the prosecution's concession that the match between the samples was unreliable and therefore inadmissible; (5) the results conceded by the prosecution to have been unreliable and deemed by the court to have been deficient were later demonstrated to have given the correct result; when Mr. Castro later pled guilty, he admitted that the blood on his watch spattered there when he stabbed the victim; (6) private labs such as Cellmark and Lifecodes are not crime labs per se, and their analysts are molecular biologists who generally have no appreciation for the characteristics of forensic samples, nor the considerations involved in testing them; and (7) because there was a guilty plea, the legal soundness of the trial court's decision will never be examined on appeal. One development, due largely to the debacle of *Castro*, has been the call for state and/or federal regulations pertaining to the use of DNA evidence.

PROPOSED REGULATIONS

A. History

In the forensic science world, regulations have long been controversial. Unlike clinical laboratories,²⁵¹ crime laboratories are not subject to regulation.²⁵² Many criminalists have long felt that there is no need for outside regulation because, in contrast to the clinical setting, crime laboratories are subject to rigorous review by courts and juries.²⁵³ While this is true, there has been much concern voiced in the legal and forensic literature regarding the need for regulation through some other mechanism.²⁵⁴

A recent report by the Committee on DNA Technology in Forensic Science, as approved by the National Research Council

251. Clinical laboratories are subject to various regulatory programs and agencies, including the Health Care Financing Administration (HCFA) of the U.S. Department of Health and Human Services and the Joint Commission for the Accreditation of Hospitals and Health Care Organizations (JCAHO). The most recent major legislation concerning clinical laboratories was the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Pub. L. No. 100-578, 102 Stat. 2901 (1988) which addresses the need for uniform federal proficiency testing standards. *See also*, 55 Fed. Reg. 20,896 (1990); 42 C.F.R. Parts 405, 416, 440, 482, 483, 488 and 493.

252. The exception to this is blood alcohol analysis, which in California is administered by the Department of Health Services under Cal. Admin. Code Title 17.

253. Interview with Gordon Deeg, Senior Criminalist, San Mateo Police Department, in San Mateo, CA (Oct. 5 1992).

254. David Helvarg, *Crime Labs Under the Microscope*, CAL. L., Dec. 1991, at 43; Simon J. Young, *DNA Evidence—Beyond a Reasonable Doubt?*, 1991 CRIM. L.R., 264. *See also*, Mark Thompson, *DNA's Troubled Debut*, CAL. L., June 1988, at 36.

(NRC),²⁵⁵ and the FBI's Response to that Report stress the necessity for national standards.²⁵⁶ The call for standards is primarily related to a desire to instill public confidence in the accuracy and reliability of DNA test results.²⁵⁷ Contrary to the disinformation published in the lay press upon the release of the Report by the Committee on DNA Technology in Forensic Science,²⁵⁸ the Committee did not conclude that "courts should cease to admit DNA evidence until laboratory standards have been tightened and the technique has been established on a stronger scientific basis."²⁵⁹ The Committee does however emphasize the need for a high level of quality control in the collection, analysis and interpretation of data. It also recommends standardization of laboratory procedures, and establishment of a mandatory accreditation program.²⁶⁰ While most of the concern is related to proficiency testing for RFLP methods, PCR is also included.

While there are problems associated with allowing the court system to determine the quality of DNA testing, there is no need for courts to stop admitting evidence obtained through properly conducted and analyzed DNA test procedures. Concerns regarding the courts' ability to determine the quality of DNA testing include the fact that courts only see a fraction of a forensic scientist's analyses.²⁶¹ Also, if the charges are dropped against a suspect, the court will never see the evidence, regardless of the analytical result. As they do not have the expertise, resources or mechanisms to control or supervise scientific quality control programs, courts should not be expected to do so. Although the court is not the ideal forum for ensuring quality science, the adversary process is a means by which those who practice "bad" science may be discredited, while those who practice "good" science may enjoy the credibility they deserve.

255. COMMITTEE ON DNA TECHNOLOGY IN FORENSIC SCIENCE, DNA TECHNOLOGY IN FORENSIC SCIENCE (1992) [hereinafter DNA TECHNOLOGY].

256. FEDERAL BUREAU OF INVESTIGATION, U.S. DEPARTMENT OF JUSTICE, RESPONSE TO THE REPORT BY THE COMMITTEE ON DNA TECHNOLOGY IN FORENSIC SCIENCE (1992) [hereinafter FBI RESPONSE].

257. John W. Hicks, *Message From the Assistant Director in Charge of the FBI Laboratory*, 19 CRIME LABORATORY DIG. 41, 41 (1992).

258. Gina Kolata, *U.S. Panel Seeking Restriction on Use of DNA in Courts*, N.Y. TIMES, Apr. 14, 1992, at A1, A1.

259. *Id.*

260. DNA TECHNOLOGY, *supra* note 255, at 97-110; Victor A. McKusick, *Opening Statement*, April 14, 1992 (unpublished).

261. See Randolph N. Jonakait, *Forensic Science: The Need for Regulation*, 4 HARV. J. L. TECH. 109, 166-172 (1991), for a discussion of the courts and the quality of forensic science.

Quality control/quality assurance²⁶² is the responsibility of those working in the laboratories. As with all professions, there are no doubt individuals within forensics who do not act responsibly nor even ethically. However, there are also many individuals within the field who take professional pride in their work, act responsibly, and treat their duty to the court with respect and honesty.

It is unfortunate that both the lay and legal literature on crime labs has stressed the problems in such a way that it would appear that every lab within the U.S. is inept and incompetent.²⁶³ This may be at least partially fostered by the fact that while many criminalists are scientists who work in the law enforcement setting, some technicians working in crime labs have law enforcement backgrounds, but no science education.²⁶⁴ This is an area of concern, as sometimes unqualified individuals attempt to undertake responsibility that is beyond their capabilities. However, just because a technician is involved in a case does not mean that their work is shoddy. Technicians perform tasks according to strict protocols and their work is overseen by a supervisor. They have no authority to make procedural changes nor the latitude to exercise judgment. In contrast, the forensic scientist or analyst is foremost a scientist who conducts the preliminary assessments of evidence as it is received, identifies the legal and/or investigative questions which must be answered in the case, and develops the analytical strategies to answer those questions.²⁶⁵ The analyst either assigns the project to someone or conducts the analysis himself/herself, and then must interpret the results. If there are any discrepancies or questions regarding the test accuracy, the approach is to re-analyze the evidence.

The ultimate results must then be explained in an impartial, non-technical way to law enforcement personnel, attorneys, judges

262. Or, as it is now often termed, "continuous quality improvement."

263. Helvarg, *supra* note 254; George J. Annas, *DNA Fingerprinting in the Twilight Zone*, HASTINGS CENTER REP., March/April 1990, at 35; Randolph N. Jonakait, *supra* note 261; Edward J. Imwinkelried, *The Debate in the DNA Cases Over the Foundation for the Admission of Scientific Evidence: The Importance of Human Error as a Cause of Forensic Misanalysis*, 69 WASH. U. L.Q. 19 (1991).

264. Helvarg, *supra* note 254, at 44.

265. George Sensabaugh, *Genetic Typing of Biological Evidence, Comments for the Cooper Amicus Brief*, CAL. ASSOC. CRIMINALISTS NEWSL., July 1987, at 11, 16.

As exemplified by the court in *People v. Young*, 381 N.W.2d 270 (Mich. 1986), some courts and experts have a misguided belief that a higher degree (e.g., Ph.D.) is a prerequisite for status as a scientist, or perhaps without a higher degree, one can't be anything more than a technician. A scientist is a person who does science, regardless of the initials after their name. The better assessment criteria are the responsibilities and expectations associated with the person's position in employment and in the scientific community to which they belong.

and juries. Thus, the forensic analyst bears a substantial burden of responsibility for knowing what to do, how to do it and how to explain it in terms understandable to the layperson. Regardless of its importance, forensics training is often not readily available to many experts.²⁶⁶ This is a great disservice to the legal system, as the expertise of many scientists goes unappreciated and misunderstood by juries and judges.

B. *Validation Studies, Standards and Proficiency Testing*

As with any new technology, validation studies and proficiency testing have been facets in the development of the AmpliType[™] HLA DQ α test kit. Concurrently, the growth of DNA analysis stimulated much discussion and study into the regulation of laboratories conducting DNA testing. "Setting standards for forensic applications of DNA testing is the most controversial and unsettled issue. Standards are necessary if high-quality DNA forensic analysis is to be ensured, and the situation demands immediate attention."²⁶⁷ In a recent case, *People v. Schwartz*,²⁶⁸ the Minnesota Supreme Court denied the admissibility of DNA test results on the grounds that the lab performing the test did not meet TWGDAM Guidelines or provide proper discovery.²⁶⁹ TWGDAM is the FBI's Technical Working Group on DNA Analysis Methods which is charged with examining quality assurance, population statistics and databanking. TWGDAM held its first meeting in November 1988, and its members include representatives from crime labs which are implementing or close to implementing DNA analysis, and commercial laboratories.²⁷⁰ It is somewhat ironic that at the time the evidence was analyzed in *Schwartz*, there were no TWGDAM guidelines available to follow.

Various professional organizations, such as the American Society of Human Genetics, the California Association of Crime Laboratory Directors (CACLD) and The Society for Forensic Haemogenetics, have published official statements or position papers regarding DNA analysis.²⁷¹ The interest in establishing a na-

266. Hollien, *supra* note 216, at 1416-1417.

267. GENETIC WITNESS, *supra* note 149, at 10.

268. 447 N.W.2d 422 (Minn. 1989).

269. *Id.* at 427-428.

270. GENETIC WITNESS, *supra* note 149, at 13; TWGDAM, *Guidelines for a Quality Assurance Program for DNA Restriction Fragment Length Polymorphism Analysis*, 16 CRIME LABORATORY DIG. 40 (1989).

271. Ad Hoc Committee on Individual Identification by DNA Analysis, The American Society of Human Genetics, *Individual Identification by DNA Analysis: Points to Consider*, 46

tionwide DNA database will help foster standardization and conformity; consistency is required if an efficient and useful computerized system is to be established.²⁷² Setting the necessary standards will require much thought and research.

As must be done with all new test systems, extensive validation studies have already been conducted on PCR. These studies have shown that DQ α typing can be accomplished without producing false positive or false negative results.²⁷³

C. AmpliType[™] Kit Development

Validation and proficiency testing have been important aspects of the AmpliType[™] kit since its inception. In 1986, the FBI approached Cetus about PCR-based forensic DNA typing. In 1989, a prototype DQ α typing system was sent to the FBI and beta testing of the Cetus AmpliType[™] kit began. From 1989-1990, over 3,000 samples were analyzed by the FBI, including fresh samples, dried stains, and samples for population studies. Research on the effects of sample exposure to light, chemical and biological agents was also performed. The AmpliType[™] kit did not become available for sale in the U.S. until February, 1990. In March, 1990, it became available in Europe, Australia and Asia. From late 1990 to May 1991, the FBI analyzed over 750 casework samples.²⁷⁴

There are also other mechanisms for proficiency testing in place.²⁷⁵ For example, CACLD conducted two rounds of blind

AM. J. HUM. GENETICS 631 (1990); *California Association of Crime Laboratory Directors, Position on DNA Typing of Forensic Samples*, CAL. ASSOC. CRIMINALISTS NEWSL., April 1988, at 4; *AABB Parentage Committee: Proposed Standards for Tests Involving DNA Polymorphisms—November 1987*, reprinted in CAL. ASSOC. CRIMINALISTS NEWSL., April 1988, at 5; *Statement of the Society for Forensic Haemogenetics Concerning DNA Polymorphisms*, reprinted in CAL. ASSOC. CRIMINALISTS NEWSL., April 1988, at 5. On Mar. 30, 1990, a resolution was adopted by the CACLD membership to endorse the TWGDAM guidelines for DNA analysis and support establishment of a national forensic data base system based on the FBI's RFLP analysis.

272. Stanley D. Rose & Tim P. Keith, *Standardization of Systems: Essential or Desirable?*, BANBURY REP 32: DNA TECH AND FORENSIC SCI. 319, 319 (1989); and Henry C. Lee & Robert E. Gaensslen, *The Need for Standardization of DNA Analysis Methods*, BANBURY REP 32: DNA TECH AND FORENSIC SCI. 217 (1989).

273. Catherine T. Comey et al., *Validation Studies on the Analysis of the HLA DQ α Locus Using the Polymerase Chain Reaction*, 36 J. FORENSIC SCI. 1633 (1991).

274. Sharon Reid, U.S. and International Use of the AmpliType[™] Kit, presented at a PCR Workshop Presented by Cetus for the California Association of Criminalists (May 18, 1991).

275. Proficiency testing is currently offered through programs such as the Collaborative Testing Service (CTS), in association with the Forensic Science Foundation (FSF). Participation in this program is voluntary and anonymous. It includes physiological fluids and samples for DNA testing. GENETIC WITNESS, *supra* note 149, at 79-80.

proficiency tests with Cellmark, Lifecodes and Forensic Science Associates/Cetus (FSA/Cetus).

D. California Association of Crime Laboratory Directors (CACLD) Tests

In the first round of 51 samples, Lifecodes obtained DNA results from 37 samples and made no errors. In its set of 50 samples, Cellmark obtained DNA results from 44 samples and made 1 incorrect match. This was a human error which was subsequently remedied by purchasing a large capacity centrifuge, thereby reducing sample manipulation. FSA/Cetus obtained results for all 50 of the samples provided. There was one incorrect match reported. Again, this was due to a human error (failure to introduce a sample into the appropriate chamber or a bubble in the vacuum apparatus), which was subsequently remedied by the routine testing of all samples in duplicate.²⁷⁶

In the second round of testing, all three laboratories received 50 samples. Lifecodes obtained results for 48 samples, while FSA/Cetus obtained results for all 50 samples. Neither Lifecodes nor FSA/Cetus reported any incorrect matches. Cellmark obtained results for 45 samples, reported that two samples gave inconclusive results and made one incorrect match.²⁷⁷

The errors made in the blind trials were all human errors, not errors that decreased the reliability of the procedure itself. In determining the admissibility of a technology, it is important to distinguish between the validity of the technology and the possibility that human error may lead to an incorrect result in the application of that technology. The statistical probabilities obtained with DNA testing (e.g., RFLP) have nothing to do with the possibility of human error in the performance of the test. While the possibility of human error is unfortunate, it can never be totally eliminated.²⁷⁸

Apparently, unlike most people (including attorneys, who may also be involved in a case involving life and death), criminalists are subject to a requirement of 100% accuracy. Not only is this unfair to the scientists who are conducting the work, it is impossible. While some commentators decry the errors made in the crime lab as

276. If significantly different results are observed for these duplicate tests, the scientist is on notice that there is a problem and the test should be repeated.

277. Report of CACLD Blind Trial #2, March 29, 1990.

278. Frederick R. Millar, Jr., *DNA: Facts and Myths*, CAL. L., July 1989 at 12 (letter to the editor).

unacceptable,²⁷⁹ it is important for those within the legal profession to recognize that crime labs are not infallible. As with all professionals, including attorneys, forensic scientists should be held to a reasonable standard of care.

The technology is ready and able to do what it was designed to do; the potential for human error(s) must be recognized and fail-safe protocols must be followed in order to avoid erroneous results. Testing samples in duplicate, saving aliquots of samples for later testing, careful labelling of samples and meticulous record-keeping all help reduce the potential for human error. Thus, there are methods by which forensic scientists may reduce the possibility of such error. These factors should be taken into consideration when the court addresses the weight, not the admissibility of the evidence.

Critics of proficiency programs argue that the results serve to emphasize the need for tighter control, including mandatory regulation through legislation.²⁸⁰ In a rather contentious debate, played out in the editorial section of "California Lawyer," it was claimed that in a recent hearing in Ventura, "the president of the California Laboratory Directors and two other association members covered up errors made by a commercial DNA laboratory in a "blind" test of its accuracy."²⁸¹ Another author, Mark Thompson also stated,

[F]or that matter, it turns out the proficiency test wasn't exactly blind. One of the genetic fingerprinting labs, Cellmark Diagnostics, initially turned in its result in a form that was "unintelligible," admitted Margaret Quo head of the Orange County Sheriff's Department crime lab, in recent testimony in a Ventura County hearing. She contacted Cellmark officials, met with them to review the problems, and allowed them to submit cleaned up conclusions three months later. That laundered report is what was released as the results of a "blind" proficiency test.²⁸²

In a response letter, CACLD DNA Committee members Jan Bashinski, Linda Hartstrom and Margaret Kuo (not "Quo") stated:

[T]he CACLD DNA Committee conducted the blind trials fairly and honestly. Neither the organization nor the individual committee members and the agencies they represent benefit financially or personally from administering the test irrespective of the outcome. To suggest that we would jeopardize our reputation to help cover up Cellmark's error is ridiculous.²⁸³

279. Jonakait, *supra* note 261.

280. GENETIC WITNESS, *supra* note 149, at 149.

281. William C. Thompson, *Letter to the Editor*, CAL. L., July 1989, at 16.

282. Mark Thompson, *Letter to the Editor*, CAL. L., July 1989, at 16.

283. Jan Bashinski et al., *More on DNA*, CAL. L., Sept. 1989, at 17.

Mr. William Thompson's statement that there was a cover up regarding the CACLD DNA proficiency study is completely false. The hearing he refers to was in *People v. Axell*,²⁸⁴ at which, on May 8, 1989, Margaret Kuo testified regarding the CACLD study.

In a responsive "Letter to the Editor," Carol J. Nelson, the prosecutor in *People v. Axell*,²⁸⁵ stated that claims made in Dr. Thompson's letter were "patently untrue." She suggests reading the transcripts of the *Kelly-Frye* hearing to determine the amount of weight Ms. Kuo's and Mr. Thompson's testimony on both direct and cross-examination should be given. For example, "he is currently earning a significant percentage of his income attacking DNA identification in courts throughout the country. As such, he is hardly an unbiased observer of what is happening in the courtroom or in the field of DNA identification."²⁸⁶

This whole sequence of letter exchanges has another layer of involvement. The letter from Mr. William Thompson was printed despite an appeal to the editor by the author to remove the inaccurate reference to a cover-up. Also, the editor was initially unwilling to publish Ms. Nelson's response letter. This led the CACLD DNA Committee to consult an attorney and send a response letter. The editor printed a portion of the letter, not including a reference to the request Dr. Thompson made to alter his original letter to the editor. Thus, in addition to the expert witnesses who travel around the country and testify against DNA testing admissibility in court, the legal press is also distorting the facts regarding cases and testimony.

As of mid-February 1990, DNA typing evidence has prevailed in virtually every legal skirmish. In spite of this overwhelming success, media portrayals, such as a January New York Times article, "Some Scientists Doubt the Value of Genetic Fingerprint Evidence," continue in their attempts to polarize and sensationalize the issues, often taking quotations out of context. If DNA's legal successes were covered as thoroughly as its few setbacks, the readership would be bored to tears. . . . Opponents of the technology point to their few limited successes, ignoring the reality of the entire legal experience to date.²⁸⁷

For the benefit of all who have read the various opinions, the facts were that the blind aspect of the testing was never compromised, there never was a "cover-up," nor has Margaret Kuo given

284. Ventura Sup. Ct. CR-23911, May, 1989.

285. Carol J. Nelson, *Letter to the Editor*, CAL. L., Sept. 1989, at 17-18.

286. *Id.*

287. Rockne Harmon, *supra* note 245, at 6.

any testimony to support this claim.²⁸⁸

E. Federal Legislation

There have been two bills introduced into Congress which deal with DNA testing. The first bill, H.R. 3371, known as the "DNA Identification Act of 1991" (Edwards bill) was introduced by Representative Don Edwards in 1991 and incorporated into the 1991 Crime Control Act passed by the House of Representatives.²⁸⁹ This bill was drafted in consultation with the FBI and the forensic community; the FBI has registered its support of the bill.²⁹⁰ The bill would authorize a DNA advisory board with the responsibility of recommending standards for quality assurance and proficiency testing to the FBI Director, who after consideration, would issue standards to serve as the basis for proficiency testing programs administered by laboratory testing organizations.²⁹¹

The other bill, H.R. 339, known as the "DNA Proficiency Testing Act of 1991" (Horton Bill), was introduced by Representative Frank Horton in January, 1991. This bill requires that states desiring to acquire equipment through federal funds, agree that their labs will meet standard guidelines and participate in proficiency testing at least every six months.²⁹² This bill proposes that the FBI publish DNA testing standards based on TWGDAM guidelines and that the FBI certify forensic DNA laboratory proficiency testing programs. The bill also provides that the DNA database program under development by the FBI in conjunction with state and local forensic laboratories be tied to the requirements of the Act.²⁹³ The FBI does not support the Horton Bill and opposes a direct regulatory role for itself.²⁹⁴ Thus, it remains to be determined who will regulate forensic labs who conduct DNA tests.

288. For accounts of the blind trials, see *Statement of the DNA Committee Regarding the Cellmark Blind Trial Report*, DNA COMMITTEE REPORT (1989).

289. DNA Identification Act of 1991 (H.R. 3371) Title X, Omnibus Crime Control Act of 1991, §§ 1002, 1003, 1004.

290. *The FBI's Responses to Recommendations by the NRC's Committee on DNA Technology in Forensic Science*, 19 CRIME LABORATORY DIG. 55-56 (1992) [hereinafter *The FBI's Response*].

291. *Id.*

292. H.R. 339 (1991).

293. This program, designated CODIS (Combined DNA Index System) is the FBI's national DNA identification system which is being designed to allow the storage and exchange of DNA records submitted by state and local forensic DNA laboratories. FEDERAL BUREAU OF INVESTIGATION, U.S. DEPARTMENT OF JUSTICE, LEGISLATIVE GUIDELINES FOR DNA DATABASES (1991).

294. *The FBI's Response*, *supra* note 290, at 56.

If not the U.S. Department of Health Services, it is likely that the responsibility will fall on the states.

F. *State Regulation*

In addition to the federal government, states have the authority to regulate forensic DNA typing by both private labs and public crime laboratories. At first blush, it would appear that the State Department of Health Services (Health Services) would be the appropriate regulatory branch to oversee forensic DNA labs, as this department is responsible for clinical and public health labs.²⁹⁵ However, regardless of the source of the regulations, it is important to remember that regulation in itself will not solve all of the problems.

For example, the experience in California crime labs in the context of blood alcohol regulation is very disturbing. The Department of Health Services oversees blood alcohol testing in the state and has set forth very exacting requirements for labs conducting these tests.²⁹⁶ There are some very real problems in the relationship between the state's labs and Health Services, which could make efficient regulation of DNA labs very troublesome.²⁹⁷

In order to avoid the regulatory problems caused by Health Services, the CACLD Professional Practices Committee prepared a legislative proposal in 1989 which would have organized a Board of Forensic Science Practices administered under the auspices of the Department of Consumer Affairs.²⁹⁸ The Board of Forensic Science Practice was not accepted by the Attorney General's Advisory Board; the Attorney General declined to sponsor legislation to create the bodies recommended by CACLD, and the Governor dropped funding for all of the proposed regional DNA labs with the exception of the Department of Justice lab in Berkeley. Thus, state regulation, at least in California, is on questionable footing.

295. With the implementation of CLIA *see supra* note 251, public health and other departments may not have the personnel nor funds to initiate involved regulatory programs for forensic laboratories.

296. For example, there are a number of pages of complex regulations governing breathalyzer tests within the CAL. REGS., tit. 17, §§ 1215-1222.2.

297. For example, while there is a mechanism for input to the Health Services Director concerning regulations regarding forensic alcohol analysis provided for in CAL. HEALTH & SAFETY CODE § 436.50 (West 1990)(amended 1992), and an "Advisory Committee" was formed, this committee has not met since 1985. Also, although procedural changes must be submitted to Health Services, it may take three years to gain approval. Telephone Interview with Kathryn Holmes, Contra Costa Crime Laboratory (Jan. 10, 1992).

298. PROFESSIONAL PRACTICES COMMITTEE OF THE CALIFORNIA ASSOCIATION OF CRIME LABORATORY DIRECTORS, REPORT TO THE BOARD (1989).

G. Self-Regulation

Self-regulation is another avenue by which the goals of regulation may be achieved without the intervention of a regulatory agency.²⁹⁹ The California Association of Criminalists has instituted a voluntary written examination for Certificates of Professional Competency in Criminalistics. The test and certification program recognize the variety inherent in criminalistics and are designed to demonstrate that the criminalist has a basic understanding of the underlying concepts, principles and other aspects of the profession.³⁰⁰ While it is a completely voluntary program, it does represent a step toward responsible self-regulation of the criminalistics profession at the local level.

Because of the diverse subject areas within forensics, a uniform, federal regulatory or proficiency testing program for all of these areas would require a large commitment of manpower, money, effort and time. For example, criminalists may be required to gain expertise in such diverse areas as protein, organic and inorganic chemistry, molecular biology, biology, firearms, arson, explosives, fingerprint comparisons, photography, computers and other electronic equipment, analysis of drugs, soil, fiber, glass, animal and human hair, human and animal sperm, bloodstains, blood spatters, paint, gunshot residue, alcohol, inks and handwriting, questioned documents, and various other disciplines.

Again, the major considerations are economic. Who will pay for all of this? Is the public willing to foot the bill for a system that in most instances already works quite well? There is a fair probability that the cost of regulating all of the subdisciplines within crime labs would be too exorbitant, especially considering all

299. GENETIC WITNESS, *supra* note 149, at 73-75. Self-regulation is also described in Jan S. Bashinski, *Laboratory Standards: Accreditation, Training and Certification of Staff in the Forensic Context*, BANBURY REPORT 32: DNA TECHNOLOGY AND FORENSIC SCI. 159 (1989). The American Society of Crime Laboratory Directors (ASCLD) is another professional forensic science organization which has established voluntary quality assurance programs through a nationwide crime lab accreditation program.

300. *An Open Letter to the Association Membership*, CAL. ASSOC. CRIMINALISTS NEWSL., Jan. 1990, at 10.

The American Board of Criminalistics (ABC) will administer the first ABC General Examination in 1993. ABC Diplomate certificates will be available for those who received the California Association of Criminalists Certificate of Professional Competency in Criminalistics. The ABC certificates will expire five years after their dates of issuance. For Diplomate status, applicants must possess a minimum of an earned baccalaureate degree or its equivalent in a natural science or an appropriately related field from an accredited institution. A minimum of two years full-time experience of active work in criminalistics is also required. "Fellow" status has additional experience and testing requirements. American Board of Criminalistics, Inc., *Certification Process*, Sept. 1992.

of the effort that would be expended to oversee such a comparatively small number of laboratories. The cost-benefit ratio would likely tilt toward non-regulation.

Regardless, the self-regulation route would require much cooperation between crime labs and law enforcement agencies nationwide, if a nationwide DNA database program is to be effective. In some aspects, it also comes back to the legal profession. While the prosecution often has no choice in the laboratory facility used, the defense may utilize any laboratory it wishes. If an attorney uses a laboratory with a questionable reputation, the work product will also seem questionable. It is very prudent to know the strengths and weaknesses of each lab available; the networks within the legal community should make this type of information readily available. With the importance of the issues involved in criminal trials, the choice of crime laboratory (and, perhaps, analytical method) would seem to warrant at least the same amount of consideration as one puts into choosing a family physician.

H. *Who Will Be Regulated, and By Whom*

Regardless of the method, proficiency testing of DNA analysis methods is on its way. It remains to be seen how standards will be implemented. Another unknown is the identity of the agency responsible for implementing these standards. For example, will federal and/or state regulatory agencies (such as Health Services) have roles to play? Hopefully, the regulations will be fair, meaningful, reasonable and practical.

While it appears likely that forensics regulations will be modelled after those for clinical laboratories, the rule-makers must remember that crime labs and clinical labs are very different entities. While they will be able to draw from the experience gained from clinical laboratory regulation in order to keep from reinventing the wheel, crime labs serve very different functions and clientele. Unlike clinical laboratories, crime labs do not have patients who pay for their services. Thus, crime labs cannot pass costs along to consumers. It is highly unlikely that defendants will be made to pay for the evidentiary analyses associated with the alleged crime. Also, who will be regulated—all crime labs, only those associated with police departments, only private labs, etc.? Thus, while regulation and proficiency testing requirements are inevitable, many questions remain, such as:

- (1) Who will pay for the proficiency testing?
- (2) Who will prepare and distribute the necessary samples?

- (3) Will it be mandatory or voluntary?
- (4) Will it apply to all laboratories or just those associated with law enforcement agencies (i.e., prosecution)?³⁰¹
- (5) What role will state agencies, such as Health Services play?
- (6) Will professional societies and organizations have a voice in regulation implementation?
- (7) Will regulation extend to other areas of criminalists (e.g., questioned documents, firearms, drug analysis, microscopy, fingerprinting etc.)? and
- (8) Will certification of criminalistics be required and if so, how will this be administered?

CONCLUSIONS AND PROGNOSTICATIONS FOR THE FUTURE

While RFLP will undoubtedly continue to be an important test method in DNA analysis both within and beyond the forensic community, it is almost inevitable that PCR will supplant it. The ease of use, the very minimal requirement of a single nucleated cell, and the elegant simplicity of the entire methodology make it particularly attractive for use in the crime lab setting. Although contamination is a potential problem, care in laboratory design and protocols will help ensure that it will not be a factor in genetic analyses of forensic samples. It is quite possible that combination systems like the "AmpFLP's" now available or direct sequencing in combination with PCR will supplant both PCR alone and RFLP.³⁰²

The development of alternative test systems, including the mitochondrial³⁰³ DNA test procedures used to identify "missing" per-

301. For example, in California, the prosecution must use an accredited laboratory for its alcohol analyses, while the defense can go anywhere, no matter how incompetent the lab is.

302. See *supra* notes 118-119 for various references other advances have also proven to be significant improvements in PCR analysis. A modified DNA extraction process using Chelex® 100 has been developed, which appears to provide better results and facilitates the combination of PCR and RFLP. Sean Walsh et al., *Chelex 100 as a Medium for Simple Extraction of DNA for PCR-Based Typing From Forensic Material*, 10 *BIOTECHNIQUES* 506 (1991). Chelex® 100, followed by PCR of DQ α and D1S80 were recently used to genetically characterize saliva from cigarette butts. This study included three cigarette butts recovered from two crime scenes (adjudicated cases) and indicated that PCR-based DNA typing is a potential method for analyzing traces of saliva left on such seemingly innocuous pieces of evidence as cigarette butts. Hochmeister, *supra* note 195.

303. Mitochondria are "organelles" contained within cells which serve as the cell's energy factory. Any energy the cell needs to survive or divide is obtained through the intensively biochemically active mitochondria. ALBERTS ET AL., *supra* note 9, at 484-500.

Unlike the other organelles within the cell's cytoplasm (with the exception of the nucleus, the cytoplasm comprises the entire area within the cell), mitochondria contain their own complement of DNA. It is hypothesized that mitochondria represent the evolutionary "remains" of bacteria which infected cells long ago and were commandeered by the cells as

sons in Argentina,³⁰⁴ also have additional potential for the forensic setting and parentage determinations.³⁰⁵ As mitochondrial DNA is inherited only through the maternal lineage, the maternal history of a person may be determined by analyzing their mitochondrial DNA.³⁰⁶ This is also of great potential value in the study of genetic diseases, especially those which have a sex-linked component.

Modified PCR methods designed to analyze RNA have proven to be extremely valuable, especially in the development of medical diagnostic tests. It is also possible that RNA analysis could be utilized in the forensic setting.

The future of DNA analysis as applied to forensics as well as the traditional areas of medical research appears quite bright. Perhaps the best advice to the legal community is to be prepared.³⁰⁷ Before deciding whether or not to use DNA analysis in court, the attorney will need to obtain many items and much information from the laboratory doing the analysis, and should if at all possible, visit the site in order to get a first-hand feel for the facility and the people doing the work.³⁰⁸

As additional techniques and refinements are developed, it is likely that the technology will continue to improve as well. As additional PCR systems are developed, they must be thoroughly characterized and proven to be reliable. During the time the kits are developed and marketed, it would be to the profession's ultimate benefit if they were subjected to the same rigorous standards as are applied to clinical diagnostic test kits. Although this would delay

energy factories. This is supported by the fact that mitochondria contain DNA which is completely independent of the DNA contained within the nucleus. *Id.* at 541-542.

304. Chris Raymond, *Forensics Experts Tackle Task of Identifying Thousands of 'Disappeared' Victims*, 261 JAMA 1388 (1989).

305. Denise S. Rath & Carl R. Merrill, *Mitochondrial DNA and Its Forensic Potential*, PROC. INT'L SYMP. FORENSIC ASPECTS DNA ANALYSIS 113 (1989).

306. Allan C. Wilson & Rebecca L. Cann, *The Recent African Genesis of Humans*, SCI. AM., April, 1992, at 68; and R. Cann et al., *Polymorphic Sites and the Mechanisms of Evolution in Human Mitochondrial DNA*, 106 GENETICS 479 (1984).

307. As legend has it, Pasteur once said, "Chance favors the prepared mind."

308. The decision whether or not to use DNA will require much thought. Be sure to get a copy of the complete lab file for the case, a list of the standard operating procedures (especially those used in your case), a curriculum vitae of the person who performed the test (it might be advisable to also get a copy of their supervisor's curriculum vitae as well), peer-reviewed articles characterizing the probes used in your case, if RFLP was done, a description of the database used in your case (including allele frequencies, sample sources, database size and any ethnic characterizations of the samples) and a description of the method to calculate frequencies and the confidence intervals applicable to the case. Be sure to also get copies of the curriculum vitae for all the expert witnesses you might use. Finally, be sure to determine if there are any relationships between the testing laboratory and the expert witnesses.

the introduction of new methods and/or genetic markers, it would help decrease the amount of court time and written criticism dedicated to the use of genetic markers in the legal system. However, regardless of its future development, a firm foundation of reliability and tremendous usefulness is in place.

ESSAY

THE TECHNOLOGICAL INNOVATION PROCESS: PATENT DOCUMENTATION AS A SOURCE OF TECHNOLOGICAL INFORMATION†

By

Ronald E. Myrick, William P. Skladony, and Ram Nath

TABLE OF CONTENTS

INTRODUCTION	356
PATENTS AS A SOURCE OF TECHNOLOGY INFORMATION....	357
THE ACCESSIBILITY OF PATENTS AS AN INFORMATION SOURCE.....	361
TECHNOLOGICAL DEVELOPMENTS IMPROVING DOCUMENT ACCESSIBILITY	366
SOME ON-LINE AND CD-ROM SEARCHING TECHNIQUES...	367
THE ROLE OF WIPO AND INPADOC	368
CONCLUSION	371
APPENDIX A - ON-LINE SERVICES.....	372
APPENDIX B - CD-ROM PRODUCTS	376

© Copyright 1993 by Ronald E. Myrick, William P. Skladony, and Ram Nath.

† The authors wish to express their gratitude to Mr. N. Rhys Merrett of Digital Equipment Corporation for his contribution to the researching, writing, and editing of this paper. The authors are also very grateful to Ms. Jane Myers and Mr. William Lawson of the United States Patent and Trademark Office; Messrs. Paul Clause and Y. Loneragan of the World Intellectual Property Organization; and Messrs. D. Dickinson and N. Fux, and Ms. S. Schiessler of the European Patent Office for their considerable assistance in promptly furnishing research materials which were most helpful in the writing of this paper.

He who receives an idea from me, receives instructions himself without lessening mine; as he who lights his taper at mine, receives light without darkening me. That ideas should freely spread from one to another over the globe, for the moral and mutual instruction of man, and improvement of his condition, seems to have been peculiarly and benevolently designed by nature.

Thomas Jefferson¹

INTRODUCTION

History has shown that it is in the nature of mankind to learn the ideas of others, to benefit from their use, and, in many instances, to improve upon them. The advisability of using the teaching of those that have already solved a particular problem is reflected in the proverbial admonition, "Don't reinvent the wheel."² Laboring over the solution to a problem which has already been satisfactorily solved by another is popularly understood to be a wasteful use of one's talents. It is better, or at least more efficient, to direct inventive energies toward improving upon a given solution, or devising a solution to an entirely different problem. Not only do ideas and information spread, the value of the ideas and information is often enhanced as they pass from one to another.

This essay focuses upon how patent documents³ can be an integral part of the process by which scientists and engineers learn from the teachings of others. More particularly, patent documents are a valuable source of technical information for advancing the understanding of a given technological art. In addition to discussing the intrinsic value of the information therein contained, this essay also discusses the ways in which patent documentation is made accessible. More particularly, the discussion highlights some recent developments in information storage and retrieval technology — such as

1. 6 WRITINGS OF THOMAS JEFFERSON, 180-181 (H.A. Washington ed.) (1854).

2. Recognizing the value of learning from others has often been metaphorically stated in terms of the person standing on the shoulders of a giant who is able to see even further than the giant himself. For example, Samuel Taylor Coleridge said, "The dwarf sees farther than the giant, when he has the giant's shoulders to mount on." SAMUEL TAYLOR, *THE FRIEND*, section i, Essay 8. And, Sir Isaac Newton said, "If I have seen further it is by standing on the shoulders of giants." SIR ISAAC NEWTON, *LETTER TO ROBERT HOOK*, February 5, 1675/76.

3. Unless otherwise noted, throughout this paper the term "patent documents" includes all published patent documents and patent related publications. Typically, such documents and publications would include: utility patents, patents of addition or improvement, dependent patents, patents of importation (revalidation, confirmation and introduction), inventors' certificates, precautional patents, secret patents when published, reissue patents, plant patents, petty patents, registrations and design patents.

the advent of Compact Disc-Read Only Memory ("CD-ROM") and on-line data accessibility. Such advancements have greatly improved the availability of patent documentation so that it is a viable, indeed convenient and economical, information resource. The essay concludes with a discussion of the role of the World Intellectual Property Organization ("WIPO") and the International Patent Documentation Center ("INPADOC") of the European Patent Office ("EPO") in the dissemination of patent documentation, especially to developing countries.

PATENTS AS A SOURCE OF TECHNOLOGY INFORMATION

Academic textbooks, scholarly treatises, journal articles, and the like, are well known to scientists and engineers as important sources of technological information. In addition to these more traditional sources of information, patent documents, which are published by and available through many patent offices around the world, likewise contain detailed technological information. Unfortunately, patents may be overlooked as an information source.⁴

Patents are a rich source of information which can be highly valuable in teaching the state of a given technological art, and thereby contribute to invention and innovation. One author stated,

Technological information is the life-blood of the innovative and inventive process and patents are also the vital source for such purpose. Patents should be, an integral part of the any data base from which relevant items are selected in the provision of both current awareness and retrospective searches. There is a need for the change in the attitude of scientists and engineers towards the patents. The academic training of technologists and scientists should be similarly oriented to make them rely equally on patent literature along with journal articles.⁵

4. L. O. Aina, *The Use of Patent Literature By Nigerian Scientists*, INSPEL, Vol 23(3), 164, 168 (1989), [hereinafter cited as "Aina"]; D. Chester, *Getting Benefits From Patents*, LASIE, Vol. 15, No. 2, Sept/Oct 1984, 2, 8-9; Sophie K. Hudnut, *Patents as Information Sources*, ONLINE '82 CONFERENCE PROCEEDINGS, 1 (1982), [hereinafter cited as "Hudnut"]; Sudarshan Kumar, *Patents as Source of Technological Information*, HERALD OF LIBRARY SCIENCE, July-October, 1984, 175, 180, [hereinafter cited as "Kumar"]; William S. Lawson, *Patents as a Source of Technological Information* paper accompanying presentation in Chicago, Ill., on Dec. 1, 1979, 1, 6, [hereinafter cited as "Lawson"]; and Susan M. Tertell, *Patents are an Overlooked Information Source*, BULLETIN OF THE AMERICAN SOCIETY FOR INFORMATION SCIENCE, October/November 1986, 24, [hereinafter cited as "Tertell"].

5. Kumar, *supra* note 4, at 181.

Another author stated,

As a source of technological information across the whole spectrum of technology, the collection of patents has no equivalent. To researchers it can be a rich source of current state-of-the-art information, new ideas, and problem

Clearly, patents can serve a very useful role in providing current information to those attempting to understand a given technology.⁶

In certain instances, however, there are limits to the technological information that can be found in patents. For example, the patent statutes of some countries have listings of subject matter which is considered nonstatutory. Most countries limit patentable subject matter to inventions of a technological nature. Examples of subject matter which is nonstatutory in certain countries include inventions relating to national security, medicines, pharmaceutical products, scientific principles (computer programs), food, as well as inventions contrary to law or morality, or injurious to health. These exclusions are often based upon the given country's perceived need to promote unrestricted technological development, resulting in the exclusion of the granting of exclusive monopolies in certain fields. In India, for instance, substances per se relating to or produced by chemical processes, (including alloys, optical glass, semi-conductors and intermetallic compounds) are non-patentable. However, methods or processes for producing such substances are patentable for a relatively short term.

In spite of these particular limitations, there are a number of key reasons why patents are a valuable source of technical information. Firstly, a fundamental prescription of patent systems around the world⁷ is that in order to be granted a patent, the applicant must

solving technology, all of which may lead to more productive research and development. Patent documents are a vital information source which should be consulted before an industrial enterprise, research and development laboratory or an individual engages in costly and time consuming experiments with the objective of developing a new patentable product.

Chester, *supra* note 4, at 4.

Citing Eckhard Derday, a third author has said,

According to Derday (1985), the technological information contained in patent documents is very crucial in the field of innovation, and since the growth of any national economy is largely influenced by the degree of its innovativeness, the full exploitation of patent information becomes obvious. Derday further emphasized that patent information is a unique instrument for the transfer of technical knowledge from developed to developing countries.

Aina, *supra* note 4, at 164.

6. On the other hand, there may be countries where a patent application for nonstatutory subject matter is preliminarily published, but not patented. Consequently, preliminary patent publications could serve as exceptionally good sources of technological information.

7. In discussing the requirements of patent systems around the world, rather than offering a sampling of the patent laws of a number of specific countries, throughout this paper the authors will refer to the provisions of "The 'Basic Proposal' for the Treaty and Regulations", compiled by the Diplomatic Conference For The Conclusion Of A Treaty Supplementing The Paris Convention As Far As Patents Are Concerned, WIPO Doc. PLT/DC/3, December 21, 1990; [hereinafter cited as "Draft Harmonization Treaty"]. Additionally, the authors will refer to the draft "Agreement on Trade-Related Aspects of Intellectual Property

disclose the invention with sufficient clarity and completeness that the invention could be carried out by a person skilled in the art to which the invention relates.⁸ In fulfilling this requirement, applicants must usually disclose at least one mode, and possibly even the best mode, of carrying out the invention.⁹ This disclosure by the applicant is often accompanied by a set of drawings which aid in the description of the invention.¹⁰ Patent laws squarely place an obligation on the applicant to disclose the invention in a manner that would enable others to practice the art. Those skilled in the art can thus consult patents and gain practical insights into the technology.

Another reason patents are a valuable source of technological information is that the patent application will include a discussion of the background art which is useful for understanding the invention.¹¹ Patent drafters often address this aspect of the patent disclosure by describing a particular problem, the drawbacks of other solutions to the problem, the inventor's solution, and the advantages resulting from that solution.¹² By consulting patent documents for technical information, one gets a concise summary of the state of the art with the invention placed in a historical context. Additionally, because each applicant is required to clearly and concisely claim the matter which comprises the invention,¹³ the patent

Rights, Including Trade in Counterfeit Goods," draft version released by GATT Director General, Arthur Dunkel on December 20, 1991, MTN.TNC/W/FA, pp. 57-90, [hereinafter cited as Draft TRIPS Agreement]. The authors have elected to refer to these two documents because to the extent that the drafts are a culmination of many years of international negotiations focused upon the harmonization of patent and intellectual property laws, they reflect a degree of consensus by the international community on the purpose, content, and format of patents. Furthermore, a review of the general principles and requirements reflected by the draft treaty and agreement provisions cited in this paper will reveal these principles and requirements that are generally implemented, in one form or another, in the various national patent laws around the world.

8. Draft Harmonization Treaty, *supra* note 7, Article 3(1)(a); and Draft TRIPS Agreement, *supra* note 7, Article 29(1). Mandating the disclosure of the invention so that the rest of society can benefit from the teaching contained in the disclosure is generally regarded as the *quid pro quo* for the exclusive rights granted to the inventor through the patent.

9. Draft Harmonization Treaty, *supra* note 7, Rule 2(1)(vi), and Draft TRIPS Agreement, *supra* note 7, Article 29. International Patent applications filed under the Patent Cooperation Treaty ("PCT"), for example, are generally required to include a description of performing the invention in the best mode. (Rule 5.1 (a) (v) PCT). Thus, patents filed in countries requiring the disclosure of the best mode will likely contain more complete information than patents from countries without a best mode requirement.

10. Draft Harmonization Treaty, *supra* note 7, Rule 2(1) (v).

11. *Id.* Rule 2(1) (ii). See also General Introduction to the Use of Patent Documents and the Technological Information Contained Therein, prepared by the International Bureau of WIPO, Doc. No. WIPO/PD/SOF/90/1, dated October 1990, 21, [hereinafter cited as "WIPO Introduction"].

12. Draft Harmonization Treaty, *supra* note 7, Rule 2(1) (iii).

13. *Id.* Article 4(2) and (3), and also see Rule 3(2) stating that "[t]he definition of the

distinguishes the new from the old by highlighting the inventor's advancement of the technology.

A further requirement for the granting of a patent, which makes patents valuable sources of technological information, is that the invention must be new and it must involve an inventive step.¹⁴ These statutory provisions insure that the patented invention was not within the public domain before the effective date on which the patent application was filed.¹⁵ Once having conceived the invention or reduced the invention to practice, the threat of the loss of rights due to public disclosure of the invention by some other source motivates inventors to file for a patent promptly. Consequently, patent documents will generally reveal information which is at the forefront of the given area of technology.¹⁶

In addition to being a source for the timely disclosure of technology, patent documents are often the only source of disclosure of important scientific or engineering information. Studies show that approximately 70%, or more, of what is disclosed in patent documents is not revealed in other publicly available sources.¹⁷ Neglecting the information in patents can therefore disadvantage the researcher, insofar as he or she could be failing to consult a unique source of significant information. Without that information, the researcher may expend considerable efforts working on a problem to which there is already an acceptable solution. For example, accord-

matter for which protection is sought shall be in terms of the technical features of the invention."

14. *Id.* Article 10(1) of Alternative A and Article 11(1), and Draft TRIPS Agreement, *supra* note 7, Article 11(1). See also WIPO Introduction, *supra* note 11, at 7.

15. Draft Harmonization Treaty, *supra* note 7, Article 11(2)(b). Many countries today have absolute novelty requirements for inventions to be patentable. To meet this requirement, the invention should not have been made part of public knowledge prior to the date of patent application. In other words, the invention cannot have been divulged to the public by an act — such as public use, non privileged disclosure, publication, sale, or manufacture — anywhere in the world, such that one skilled in the art would be able to practice the invention from information obtained from the act. Other countries, such as Japan and the U.S., have relative novelty requirements whereby pre-filing publication of the invention anywhere in the world can result in the loss of novelty, but in order for a public use to result in the loss of novelty it must occur within the country. In the United States inventors are also given a one year grace period during which they may file a patent application even after public disclosure or use. See 35 U.S.C. sec. 102(b). In Japan, Article 30(1) of the Patent Law provides a six-month grace period in respect of printed publications (and certain other written disclosures) of the invention attributable to the applicant, provided written request for the application of Article 30(1) is made when the application is filed. Because failure to file within the grace period will result in a loss of rights, even under the relaxed standards of a relative novelty country, there is, nonetheless, motivation to file for a patent promptly.

16. WIPO Introduction, *supra* note 11, at 7.

17. Chester, *supra* note 4, at 5; Hudnut, *supra* note 4, at 1; Lawson, *supra* note 4, at 6; Tertell, *supra* note 4, at 24; and WIPO Introduction, *supra* note 11, at 8.

ing to one author international studies have estimated that at least 10% of all R&D expenditure is duplication of what could have been determined through a patent search. This translates into the waste of approximately 100 million R&D dollars per year in Australia.¹⁸

Patent laws require the invention to be industrially applicable.¹⁹ This insures that the invention has some utility. Frequently, the patent will include not simply concepts, but also detailed information on the possible practical applications of the invention.²⁰ Moreover, the expense associated with securing and maintaining a patent will generally insure that the invention has some perceived value, since the patentee would not incur that expense otherwise. Patents therefore include relevant technological information, which will have a practical utility for members of the engineering and scientific communities.

THE ACCESSIBILITY OF PATENTS AS AN INFORMATION SOURCE

Patent documents are inherently valuable to scientists and engineers because of the technical information they contain. However, due to the sheer volume of patent documents published around the world each year,²¹ their value as an information re-

18. Chester, *supra* note 4, at 6.

19. Draft Harmonization Treaty, Article 10(1), Alternative A, and Draft TRIPS Agreement, Article 27, *supra* note 7.

20. WIPO Introduction, *supra*, note 11, at 8.

21. A report of the World Intellectual Property Organization, reveals that in 1990, the year for which the most current data is available, the total number of patents applied for in the 82 nations covered by the report was 1,663,280. During that year the total number of patents granted in the 82 nations was 548,304. *Intellectual Property Statistics 1990*, Publication A of the World Intellectual Property Organization, Doc. No. IP/STAT/1990/A (Publication A).

Focusing upon the United States, for example, statistics of the United States Patent and Trademark Office ("USPTO") reflect the trend toward more patents being applied for and granted, suggesting that an increasing amount of technical information is revealed in patents.

<i>Year</i>	<i>No. of App. *</i>	<i>No. Granted Pats. *</i>
1985	117,006	71,661
1986	122,433	70,860
1987	127,917	82,952
1988	139,825	77,924
1989	152,750	95,539
1990	164,558	90,366

* Figures only relate to utility patents.

During the fiscal year ending September 30, 1991, the USPTO had granted 92,474 utility, plant, and reissue patents.

In addition to patents, patent offices also collect and index other publications, which are used in prior art searches, along with the patents. Again referring to the USPTO, statistics reveal the daunting volume of documents that are added to the collection of just one patent

source would be greatly diminished if they could not be conveniently and efficiently accessed by those interested in using them.

Fortunately, patent documents are catalogued in a manner that is designed to facilitate their easy access. Ease of accessibility is due in part to the classification of documents within the given patent system, and also to the typically uniform format by which individual patent documents tend to be structured. Accordingly, an individual who is familiar with general research techniques can quite readily access documents within the system, and quickly assess the usefulness of a given document.

Naturally, the first concern of the researcher interested in using patents is how to access the system. The classification of patents, according to their respective areas of technology, is the means by which individual documents are cataloged, and therefore accessed.²² Using a variety of search aids,²³ the researcher can find the class and subclass in which the given technology is catalogued. Frequently, a given technology area may be catalogued in more

office. For example, during the years shown, the USPTO added the following U.S. and non-U.S. documents to its collection.

<i>Year</i>	<i>U.S. Docs.</i>	<i>Non-U.S. Docs.</i>
1985	285,000	359,000
1986	291,000	373,000
1987	353,000	363,000
1988	506,000	378,000
1989	436,000	381,000
1990	458,000	512,000

Patent Type Summary Report as of December 31, 1990.

As of December 31, 1991, the USPTO housed a total of 31 million U.S. and non-U.S. documents, comprised of patents and other printed publications.

Finally, although it is not known precisely how many patent documents have been published *in toto*, estimates place the number at about 30 million, with an additional 1 million patent applications and granted patents being added each year. WIPO Introduction, *supra* note 11, at 6 - 7; Chester, *supra* note 4, at 8.

22. Presently, over 50 countries apply the International Patent Classification ("IPC") system to their patents. Also, as of January, 1990, the IPC divided technology into 8 sections, 118 classes, 616 subclasses, 6,871 main groups and 57,324 subgroups, for a total of 64,195 divisions or subdivisions. "The International Patent Classification (IPC), Its Philosophy and Use," Prepared by the International Bureau of WIPO, Doc. No. WIPO/PD/SOF/90/2, dated October 1990, [hereinafter cited as "WIPO Classification"], at 4 and 6. Also see WIPO Introduction, *supra* note 11, at 10 - 12. Current versions of the IPC are available in English and French. There are also translations into other languages, such as Chinese, German, Hungarian, Japanese, Korean, Polish, Portuguese, Spanish, and Thai, which makes the use of IPC relatively economical and simple for use by searchers from developing and industrialized countries alike. It is estimated that more than 90% of the patent documents in the world bear the IPC symbols and can be accessed therefrom.

In addition, the patent system in a given country will also have its own classification system, and there are naturally variations in their respective levels of sophistication. As of January, 1992, the United States Patent Classification System has 415 classes and 127,194 subclasses for its patent documentation. Issued U. S. patents include within the bibliographic

than one class or subclass, which may make the research project somewhat more complex, but still manageable. Having located the appropriate classes and subclasses, the researcher can then retrieve the individual documents within the class or subclass for review.²⁴

The researcher is further assisted by the fairly uniform format by which standard information is presented in the patent.²⁵ Patent formats include a title,²⁶ an identification of the technical field to which the invention relates,²⁷ a discussion of the background art,²⁸ a description of the invention with reference to the background

information the appropriate U.S. Patent Classification numbers as well as International Patent Classification ("IPC") numbers.

The European Classification ("ECLA") is a variation and an extension of the IPC developed by the European Patent Office. The ECLA system comprises 65,000 subdivisions of the IPC and additionally 39,900 more detailed subdivisions.

There are also private entities which have developed their own classification system. For example, the Derwent classification system, developed by Derwent Publications Limited, is well organized and continually updated. Derwent provides instruction manuals and a World Patent Index comprising listings of patent documents from thirty countries/groups including EP and PCT. The system also provides views of trends in technological innovation through patents-statistical-analysis. Derwent has international branches which allow access to its database from one of several geographic locations in the world.

Conversion tables for interconnecting patent classification systems of different countries have been developed, but are not as effective as would be desired by a modern searcher or user, because of the diversity in the approach to the classification by different countries.

23. The searching of patents classified according to the IPC is accomplished by reference to a Guide which explains the layout, use of symbols, principles, rules and application of the IPC, as well as a survey of the classes and a summary of the main groups. WIPO Classification, *supra* note 22, at 5.

In the United States the Index to the U.S. Patent Classification gives an alphabetical listing of subject matter headings or descriptions. Additional sources such as the MANUAL OF CLASSIFICATION contains the classification schedules, while the U.S. PATENT CLASSIFICATION DEFINITIONS gives a detailed definition of what is included in or excluded from a particular classification, adding useful search notes. Also see Hudnut, *supra* note 4, at 5; Lawson, *supra* note 4, at 11; and Tertell, *supra* note 4, at 24-25.

Yet another information tool available in the United States is the *Official Gazette* ("OG"), which is published weekly by the USPTO, and contains a summary of each patent issued during the week, arranged according to the subject matter of the patent. Typically, the OG entry for a given patent will contain the abstract of the invention and a representative illustration of the invention taken from the patent.

24. The U.S. PATENT CLASSIFICATION SUBCLASS LISTING lists the patent numbers which fall within a certain classification so that the researcher can then retrieve the documents. See Tertell, *supra* note 4, at 25.

25. WIPO Introduction, *supra* note 11, at 7.

26. Draft Harmonization Treaty, *supra* note 7, Rule 2(1).

27. *Id.* Rule 2(1) (i).

28. *Id.* Rule 2(1) (ii). A description of the background art is commonly found in the patents of most countries, even though the inclusion of such is not always mandated by statute. There are, however, patent systems which require the discussion of relevant prior art in sufficient detail. The European Patent Convention is an example of one such system. Rule 27, chapter II, Provisions Governing The Application, Implementing Regulations to Part III of the European Convention.

art,²⁹ an explanation of the invention by reference to examples, where appropriate, and by reference to the drawings,³⁰ and finally the claims.³¹ In addition, patents typically have an abstract which contains a concise description of the invention, sometimes including a drawing or figure.³² Abstracts are often translated into a number of different languages. Therefore, even if the patent is in a language which is not understood by the researcher, a translated version of the abstract may be consulted. Particularly, by reference to the title and the abstract, the researcher can easily and accurately determine whether the patent document is relevant.

Patent documents contain so-called bibliographic data that provides useful peripheral information. For example, the bibliographic data typically includes an identification of the inventor, the assignee, if any, the filing date, the publication date, and the issue date.³³ Such information can assist the researcher in determining the vintage of the technology involved. This may have a direct bearing on its usefulness. It can also assist the researcher in locating the inventor or assignee, to have direct discussions relating to the invention if necessary or desirable, or to obtain a license to avoid infringement. Such information also provides an indication of which individuals or corporate entities are involved in particular areas of technology.

The bibliographic data might further include, in addition to a national classification, the international classification of the invention. Using the classification, a searcher could further refine a search by narrowing the examination to: patents in a particular country; patents in a particular language; or patents which belong to a specific assignee.

The bibliographic data often also includes references to other patents and prior art documents which were considered by the pat-

29. *Id.* Rule 2(1) (iii).

30. *Id.* Rule 2(v) and (vi).

31. *Id.* Article 4. There are patent systems which permit the filing of provisional patent applications with no claims, to be followed by a complete application with claims. If no complete application is filed on time, the provisional application, without claims, might be published, laying open the complete specification. Such a system exists in the United Kingdom. In any event, a searcher must be aware that for an unexpired patent, the onus not to infringe is upon the user of the information.

32. WIPO Introduction, *supra* note 11, at 8 and 13. Also, information on abstracts may be obtained from the following sources:

— The Japanese Patent Office, Chiyoda-Ku, Tokyo, Japan.

— Derwent Publications Ltd., Rochdale House, 128, Theobalds Rd. London WC1X-8RP, U.K.

— Chemical Abstracts Service, Ohio State University, Columbus, Ohio, 43210, USA.

33. *Id.* Article 6(1), and *see also* WIPO Introduction, *supra* note 11, at 8.

ent examiner in connection with the examination of the patent application. Using the listed references, a searcher may obtain other patents and nonpatent literature, such as technical publications, articles and other documents, which might be relevant in the context of the particular invention in question. It is also possible to determine whether a given document has been cited as a reference in subsequently published patent documents, which further expands the linkwork of successive publications. All such information can be invaluable to the researcher in efficiently ferreting out the other documents which contain information on related technology. In addition, through the use of the cross-references, the researcher can develop a confidence that all, or virtually all, related sources of information have been consulted.

The documents that comprise the data collection of a given patent office are generally publicly accessible at the central patent office in any given country. So too are the various search aids that assist in finding relevant documents. To the extent that the central patent office of a given country is physically accessible to only a small percentage of the residents of the country, and an even smaller percentage of the world community, many patent offices are committed to the dissemination of patent information by expanding the availability of the documents through a number of different methods.³⁴

For example, within a given country, there may be a number of patent depository libraries which are geographically dispersed so that persons in other regions of the country will have access to many, but not all, of the same documents contained in the central patent office's collection.³⁵ In order to achieve world-wide distribution, the central patent office of one country may have exchange agreements with other countries through which they respectively exchange documents.³⁶ Through this distribution system, patent documents are made more accessible.

Patent offices around the world may be strongly committed to

34. William S. Lawson, *USPTO Perspectives - Use Automation Products Available From USPTO*, [hereinafter cited as "Lawson Perspectives"], for presentation at AIPLA mid-winter meeting, (January, 1992) at CI2, describing the mission of the USPTO.

35. In the United States, for example, there are presently over 70 Patent Depository Libraries in 45 states and the District of Columbia. See Lawson Perspectives, *supra* note 34, at CI2.

36. The United States has such exchange agreements with approximately 35 other countries resulting in the USPTO annually sending out a total of 51 sets of U.S. documents, either on paper or on microfiche. Given that the USPTO publishes on the order of 100,000 documents per year, over 5,000,000 patent documents are distributed around the world by the USPTO annually.

improving the availability of patent documents to their own citizens and the world community. Historically, however, there were significant impediments to the achievement of this objective. Traditionally, patent documentation was accessed manually using paper copies, microfilm, or microfiche. The searcher scrutinized abstracts or full texts in order to locate patents that were of interest. Thus, the search process was performed manually, and was understandably slow. In addition, unless the searcher was geographically situated close to the central patent office, or a depository library, accessibility was limited.

TECHNOLOGICAL DEVELOPMENTS IMPROVING DOCUMENT ACCESSIBILITY

There are presently a wide variety of data bases³⁷ which contain information covering patent documents. Recent technology developments have enhanced the means by which the information contained in the data bases are made available on both a local and remote basis. The availability of these improved sources and access services continues to spread. Two important technological developments which have improved the availability of patent documents are on-line access to computer stored data bases and access through CD-ROMs.³⁸

So-called "on-line" access to computer stored data bases refers to access over some type of telecommunications network. Such data bases are made accessible to subscribers of the given on-line service by the private entity which makes the service available.³⁹ Subscribers to the service may be charged one time or annual subscription fees, as well as actual use fees which are computed on the basis of the amount of time one is actually connected to the on-line resource, not unlike a regular telephone charge.

Typically, an on-line data base enables the searcher to direct the inquiry to the various items of bibliographic data, such as inventor's name, patent owner, title, abstract, classification, filing date, or publication date. Therefore, if a researcher was not familiar with

37. Generally, a data base is a collection of information which pertains to a given subject area or topic. The individual records within the data base are uniformly formatted so that each record contains the same type of information, though obviously not the same information, for each entry. Examples of data bases for patent documents, and the type of information contained in each data base are given in Appendix A.

38. *Lawson*, *supra* note 34, at CI6 - CI10; *Tertell*, *supra* note 4, at 25.

39. Examples of such private parties which provide on-line services are Dialog, Orbit, Patolis, and STN. Also see Appendix A for a selected listing of the data bases which they respectively provide, and their addresses and telephone numbers.

the most relevant classification of the technology which needs to be searched, these other data fields can be searched to identify one or more patents in the target area of the search.

In addition to accessing data bases on-line, the same or other data bases can be stored and accessed on CD-ROM.⁴⁰ A CD-ROM provides a very convenient, compact, electronic medium for storing relatively large amounts of information in word searchable form. For example, about 1000 U.S. patents could be stored in full text and image form on a single CD-ROM disc. In their protective plastic cases, 100 CD-ROM discs storing about 100,000 U.S. patents could be housed in less than three and a half feet of shelf space.⁴¹ The use of CD-ROMs requires a PC-AT computer, a high resolution screen, a CD-ROM drive and printer. The printing of facsimile images will require a laser printer.

CD-ROMs which contain full bibliographic information, text and drawings in facsimile form, are available to facilitate local reproduction of individual copies in a quick, inexpensive manner. At present, the availability of such CD-ROMs is limited to U.S., EPO, PCT, German and U.K. patent documents.⁴² There are also CD-ROMs which contain bibliographic information, abstract and representative drawings in facsimile form, or bibliographic information only. Naturally, the type of information on a given CD-ROM will determine the limits of the search one is capable of performing using that resource.

SOME ON-LINE AND CD-ROM SEARCHING TECHNIQUES

It should first be noted that although patent documents can be accessed and searched through a variety of known data-bases all over the world, the consistency and value of the search results depend heavily on the limitations of the data-base and the manner of searching. Additional variables affecting the search relate to the peculiarities and the features of the accessed patent system, and the specific kinds of patents being accessed.⁴³

40. A selected listing of CD-ROM products and the sources that make the products available are shown in Appendix B.

41. *Lawson, supra* note 34, at CI8.

42. *Lawson, supra* note 34, at CI10.

43. For example, searchers should be aware that applications filed under the European Patent Convention ("EPC") or the Patent Cooperation Treaty ("PCT") will typically result in national applications/patents in designated countries. EPC/PCT applications are, however, subject to preliminary publication at about eighteen months after the priority date of the respective application. Such preliminary publications also are documented and stored in databases and can be accessed during a search. EPC/PCT applications in the course of their prosecution enter the national stage, and, if granted, culminate in national patents which are

Nonetheless, the availability of patent information on CD-ROMs and on-line data bases provides alternatives to local searching. For example, using CD-ROMs, a local search and retention facility can be set up to permit full text document reproduction without incurring the expense associated with accessing on-line data bases. Searches can be conducted using CD-ROMs containing only bibliographic data, titles and/or abstracts to locate patents of interest. CD-ROMs storing full images can then be used to provide screen displays or hard copy full text and drawings of those patents. One disadvantage of this approach is that despite their storage capacities, several CD-ROMs may need to be searched to cover a desired period or range of patents, thus slowing down the search process.

Alternatively, a search could be conducted using an on-line data base service to identify patents of interest from one or more data bases. Once those patents are identified on line, one could then access those patents from a full text/image CD-ROM and reproduce the complete patent. This approach facilitates a more comprehensive search over a range of patents from various sources while minimizing the expense through local reproduction and review of full text copies.⁴⁴ However, the cost of accessing on-line data bases over international data links could be quite significant.

THE ROLES OF WIPO AND INPADOC

The World Intellectual Property Organization ("WIPO") plays a central role in promoting the use of patent documentation as a source of technological information. WIPO promotes the free exchange of patents and related publications between patent offices all

documented and classified just like other national patents, by interested agencies, eg., patent offices, WIPO and other data bases. The searcher will be able to observe the differences, if any, in the text and other portions of the preliminary publication as compared with those in the final granted patent.

44. By way of example of the practical use of these on-line and CD-ROM resources, the Law Department of Digital Equipment Corporation in Maynard, Massachusetts, USA, currently uses on-line data base services to locate English language equivalents of non-English language patents, such as prior art references cited in Patent Office Search and Examination Reports. Also under consideration is the expanded use of on-line patent data bases and CD-ROMs for retroactive searching purposes, such as evaluating the novelty of invention disclosures as part of a decision making process prior to filing the patent application. CD-ROMs offer an attractive basis for self-contained on-site bibliographic and abstract searching and full text patent documentation retrieval, particularly for USPTO and EPO patent documentation. However, CD-ROM abstract searching currently is of limited value because CD-ROMs containing abstracts are available only for the past few years. For example, CASSIS/BIB contains only abstracts for the most recent previous three years while ESPACE CD-ROM products do not extend back before 1989.

over the world. Patent publications both in paper form and in microform are exchanged under various arrangements, with the flow of information designed to address the needs of developing countries.⁴⁵

Additionally, WIPO has assisted the patent offices of some countries and organizations, such as those of Brazil and the African Intellectual Property Organization, to modernize the documentation of their information and records. Representatives from developing countries have been invited to attend training courses arranged by WIPO which discuss the use of technological information contained in patent documents.

WIPO oversees a permanent committee on patent information ("PCPI"). PCPI comprises working groups which provide information to developing countries on requested searches, general information, and standards. WIPO also maintains a program which provides developing countries state of the art searches covering the technology in a requested area. This service relies upon the assistance of several donor countries, such as Germany, Sweden, Austria, which have contributed both time and energy.

Another significant contribution of WIPO is the publication of guidelines for establishment of regional patent information and documentation centers ("PIDC's"), to help promote the dissemination of technological information to developing countries. The document entitled "Guidelines for the Organization of a Patent Information and Documentation Center," was updated in 1987. The two objectives of the guidelines are first, to facilitate "the access of developing countries to technical information already existing in documents such as those concerning patents and other information important to the transfer and use of technology;" and second, to encourage developed countries to "make available in a systematic manner, in accordance with their national laws and regulations, the results of their research and development relevant to the social and economic development of developing countries."

WIPO has also published the so-called INID code which pertains to "recommendation concerning bibliographic data relating to patent documents," and a user oriented guide to the International Patent Classification system. The guide includes four key sections

45. One method by which patent documentation could become more accessible in developing countries is through the creation of Patent Information Document Centers ("PIDC") under guidelines published by WIPO. It seems desirable for WIPO to start PIDCs in developing countries where a PIDC does not exist and thus get the local government involved in technology acquisition/transfer efforts according to need.

of interest to developing countries, namely iron and steel, fertilizers, agro-industries, and agricultural machines and implements, for obtaining solutions to certain technical problems.

In addition to WIPO, a comprehensive international referral service relating to patent documentation is provided by the International Patent Documentation Center (INPADOC) located in Vienna. INPADOC was created in 1972 under an agreement between WIPO and the Republic of Austria. It is now operated as part of the Patent Information Directorate of the EPO.

INPADOC stores and updates basic bibliographic data on the published patent documents of a large number of countries, organizations, or other entities.⁴⁶ The bibliographic data processed and stored by INPADOC is available to government authorities and the public. Due to the comprehensiveness of the bibliographic data, documentation pertinent to specific technical categories and all corresponding patent documents filed for the same invention can be located. Using this information and the link established by the common convention priority date, a "family" of patents can be identified.⁴⁷ Once the members of the family of patents are identified, it can be determined whether the patent is available in a given language. Also, the number of members in the family, which is determined by the number of different countries in which the patent was filed, will give some indication of the perceived importance of the invention.

INPADOC presently makes available a Patent Register Service ("PRS") which gives information on the legal status of patent applications and the granted patents for 12 countries and organizations.⁴⁸ The INPADOC Patent Gazette (IPG), a weekly publica-

46. Those countries, organizations, or other entities are: Argentina, Aripo, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Peoples Republic of China, Cuba, Cyprus, Czechoslovakia, Denmark, Egypt, Finland, France, Germany, Greece, Hungary, India, Ireland, Israel, Italy, Japan, Kenya, Luxembourg, Malaysia, Malawi, Mexico, Monaco, Mongolia, Netherlands, New Zealand, Norway, Philippines, Poland, Portugal, Republic of Korea, Romania, South Africa, Soviet Union, Spain, Sweden, Switzerland, Turkey, United Kingdom, United States of America, Vietnam, Yugoslavia, Zimbabwe, the European Patent Office (applications for European patents), the International Bureau of WIPO (international applications under the PCT). The UK patents registered in Hong Kong and Singapore are also recorded.

47. Once a searcher locates a patent document using its classification, by calling the family of patent documents all of which relate to the same priority document, the patent document of a particular language or a particular country can be identified. The researcher should be aware, however, that unless the data base includes non convention countries, it is likely that the patents in the non convention countries, such as Taiwan, India, and Pakistan, would not be included in the family listing.

48. Those countries or organizations are: Austria, Belgium, Switzerland, Germany,

tion, has four indexes: a numerical index; an IPC symbol index; an index of names of applicants and owners; and an index of inventors names. Each index contains references to all patent documents entered in the INPADOC data bank during the proceeding week. Users can thereby readily monitor developments in a particular technical field, or the activities of a given firm, enterprise or inventor. INPADOC bibliographic data and legal status data for patent documents are available on microfiche and tape while the IPG is available on microfiche.

CONCLUSION

Patents are a well-indexed and well-classified source of technological information. They can therefore be beneficially used by individual researchers, corporations, research and development organizations, universities, governments, and others, to learn the technology revealed therein. Patent documentation can also be a useful tool for planning development, allocating funding, and producing statistical information. Whereas patent documentation has traditionally been an underutilized information resource, perhaps due to its more remote accessibility, modern technology has greatly enhanced its availability. Moreover, accessibility is made even easier due to organizations, such as WIPO, which are chartered to improve the wide distribution of patent documentation and the dissemination of technological information. To the extent that the course of history amply demonstrates the value of learning from the teachings of others, it would certainly be undesirable for patents to remain an overlooked source of technological information, especially by developing nations.

APPENDIX A - ON-LINE SERVICES

The following is a selected listing of several data bases and a brief statement of the scope of the contents of each. Also listed are the source entity responsible for maintaining the data bases, as well as the on-line service through which the data base is accessible. With respect to the source entities and each on-line service, the address and telephone numbers are provided. Address, telephone, and FAX numbers are also included for providers of the on-line services.

*Data bases:**INPADOC*

This data base contains bibliographic information for patent documentation from over 50 countries and organizations. The source is the European Patent Office, and it is available on-line through DIALOG, ORBIT, STN and PATOLIS.

JAPIO

This data base contains English language bibliographic information and abstracts of published, unexamined Japanese patent applications published since 1976. The source is the Japan Patent Information Organization, and it is available on-line through ORBIT.

WORLD PATENT INDEX

This data base contains bibliographic information, abstracts, and special subject classification codes for patent documents from 31 patent issuing authorities. The source is Derwent, and it is available on-line through DIALOG, ORBIT and QUESTEL.

*Addresses and telephone numbers for selected sources:**European Patent Office*

Principal Directorate, Patent Information, European Patent Office, EPIDOS-INPADOC Services, Moellwaldplatz 4, Postfach 163, A-1041 Vienna, Austria. (From January 20, 1992). Telephone: 43-1-5261201; FAX: 43-1-52126-1493.

Japan Patent Information Organization

Japan Patent Information Organization, International Department, Sato-Dia Bldg.; 4-1-7 Toyo, Kotu-Ku, Tokyo 135, Japan. Telephone: 81-3-5690-5555; FAX: 81-3-5690-5566.

United States Patent and Trademark Office

U.S. Patent and Trademark Office, Office of Electronic Information Products and Services, Crystal Mall 2, Room 304, Washington, D.C. 20231, U.S.A. Telephone: 1-703-557-5652.

*Addresses and telephone numbers for selected on-line services:***DIALOG****Main office:**

U.S.A. - Dialog Information Services, Inc., 3460 Hillview Avenue, Palo Alto, CA 94304, United States. Telephone: 415-858-3785; FAX: 415-858-7069.

Other offices:

ARGENTINA - In/Base Argentina S.A./DIALOG, Paraguay 1345, Piso 8, Of. C-D, Buenos Aires. Telephone: 54-1-814-4258; FAX: 54-1-814-4258.

AUSTRALIA/NEW ZEALAND - Insearch Limited/DIALOG, P.O. Box 123, Broadway, Sydney, NSW 2007. Telephone: 61-2-212-2867; FAX: 61-2-281-5427.

BRAZIL - PTI/DIALOG, Publicacoes Tecnicas Internacionais Ltda., Rua Peixoto Gomide 209, 01409 Sao Paulo SP. Telephone: 55-11-257-2157; FAX: 55-11-258-6990.

CANADA - Micromedia Ltd./DIALOG, 158 Pearl Street, Toronto, Ontario M5H 1L3. Telephone: 416-593-5211; FAX: 416-593-1760

CHILE - Empresa Nacional de Telecomunicaciones, S.A./DIALOG, (ENTEL-CHILE), Santa Lucia #360, Piso 8, Santiago. Telephone: 56-2-71-21-21; FAX: 56-2-690-2638.

DENMARK - DataArkiv/DIALOG, Glentevej 65, DK-2400 Copenhagen NV. Telephone: 45-38-33-52-10; FAX: 45-31-19-93-51

FINLAND - Esselte Micromedia/DIALOG, Italahdenkatu 22 BA, 00210 Helsinki. Telephone: 358-0-692-6419; FAX: 358-0-692-7820

FRANCE - Learned Information/DIALOG, 75 avenue Parmentier, 75011 Paris. Telephone: 33-1-40-21-24-24; FAX: 33-1-40-21-24-00

GERMANY - EXIT Datenbankdienste/DIALOG, Graf-von-Stauffenbergstrasse 19, D-4800 Bielefeld 1. Telephone: 49-521-16-10-21; FAX: 49-521-10-99-00

HONG KONG - Information Services/DIALOG, 50 F'Aguilar Street, Central, Hong Kong. Telephone: 852-868-0877; FAX: 852-845-0141.

INDIA - Informatics (India) PVT Ltd./DIALOG, PB No. 360, Malleswaram 11th Cross, Bangalore, India 56003. Telephone: 91-812-845-2041.

ISRAEL - Teldan Information Systems Ltd./DIALOG, 7 Derech

Hasholom, Tel-Aviv, Israel 67892. Telephone: 972-3-25-00-73; FAX: 972-3-62-39-09.

JAPAN - KINOKUNIYA COMPANY LTD., ASK Information Retrieval Services, P.O. Box 55 Chitose, Tokyo 156. Telephone: 81-3-439-0123; FAX: 81-3-439-1093.

JAPAN - MARUZEN CO. LTD., MASIS CENTER, P.O. Box 5335, Tokyo International 10031. Telephone: 81-3-271-6068; FAX: 81-3-271-6082.

KOREA - Data Communications Corporation of Korea, Sales and Marketing Division, 10th Floor, Insong Building, 194-45, Hoehyundong 1 GA, Choong-Ku, Seoul. Telephone: 82-2-791-1114; FAX: 82-2-796-8811.

MEXICO - Asesores Especializados en Informacion y Documentacion, S.C., AEID/DIALOG, Ceres 43, Col. Florida, 01030 Mexico, DF. Telephone: 52-5-534-8950; FAX: 52-5-534-8950.

NORWAY - AXESS A/S/DIALOG, P.O. Box 86 Bryn, 0611 Oslo 6. Telephone: 47-2-72-12-70; FAX: 47-2-72-12-66

SAUDI ARABIA - Arabian Advanced Systems, AAS/DIALOG, P.O. Box 20129, Riyadh 11455. Telephone: 966-1-476-6337.

SPAIN- Editorial Garsi SA/DIALOG, Numancia, 85-87, bajo, 08029 Barcelona. Telephone: 34-93-322-99-11; FAX: 34-93-322-96-52

SWEDEN - DataArkiv/DIALOG, Box 1502, S-171 29 Solna. Telephone: 46-8-705-1300; FAX: 08-82-82-96

SWITZERLAND - Centredoc/DIALOG, Rue Brequet 2, CH-2007, Neuchatel. Telephone: 41-38-205-639; FAX: 41-38-25-48-73

U.K. - Learned Information/DIALOG, P.O. Box 188, Oxford OX1 5AX, United Kingdom. Telephone: 44-865-730-275; FAX: 44-865-736354

ORBIT

Main office:

USA - Maxwell Online, Inc., 8000 Westpark Drive, McLean, VA 22101. Telephone: 1-703-442-0900; FAX: 1-703-893-4632.

Other offices:

AUSTRALIA - Maxwell Online, Locked Bag 44, Botany, NSW 2019. Telephone: 61-2-316-9631; FAX: 61-2-316-9485.

JAPAN - USACO Corporation, 13-12 Shinbashi 1-Chome, Minatoku, Tokyo, 105. Telephone: 81-3-3502-6471; FAX: 81-3-3593-2709.

KOREA - Samsung Co., LTd., Business Development Dept., Taepyong-no. 2-GA, Chung-gu, Seoul, Korea 100-102. Telephone: 82-2-751-2542; FAX: 82-2-751-2776.

U.K. - Maxwell Online, Achilles House, Western Avenue, London W3 0UA, England. Telephone: 44-81-992-3456; FAX: 44-81-993-7335

PATOLIS

Japan Patent Information Organization, Sato Dia Bldg., 4-1-7, Toyo, Kotu-Ku, Tokyo 135, Japan. Telephone: 82-3-5690-5555; FAX: 82-3-5690-5566.

QUESTEL

Main Office:

FRANCE - Questel, 55 Avenue des Champs Piereux, 92012 Nanterre Cedex, France. Telephone: 33-1-46-14-55-55.

STN

Main Office:

GERMANY - STN International, P.O.Box 2465, D-7500 Karlsruhe 1. Telephone: 49-7247/82-45-66; FAX: 49-7247/29-68.

Other offices:

AUSTRALIA - CSIRO Information, Resources Unit, 314 Albert Street, East Melbourne, Victoria. Telephone: 03-418-7333.

U.S.A. - STN International, 2540 Olentangy River Road, Columbus, OH 43202. Telephone: 614-421-3698; FAX: 614-421-3713

Access to these on-line services from countries throughout the world is available through Public Data Networks ("PDNs") which facilitate international data communication. PDNs are generally run by the national telecommunication authority of the country. Subscribers to a national PDN can then use international networks such as DIALNET, TYMNET or SprintNet to connect to an on-line service. DIALOG, ORBIT and STN can be accessed via TYMNET and SprintNet; PATOLIS via Venus-P.

APPENDIX B - CD-ROM PRODUCTS

The following is a selected listing of sources which maintain and provide CD-ROM products, and the contents of those products. Included with each title is a brief description of the scope of the contents of the CD-ROM, and finally a listing of the addresses and telephone numbers of each source.

CD-ROM products of the European Patent Office:

ESPACE-EP

This CD-ROM product contains the complete EPO patent specifications published since 1989. Each is stored in image form so that the text, drawings, and formulae can be reproduced exactly as the original using a laser printer. All bibliographic data on the title pages are index coded and title searches can be made in English, French or German.

ESPACE-FIRST

This CD-ROM product contains the first pages of EPO and PCT patent applications published since 1989. Each is stored in facsimile format with searchable bibliographic information and abstracts.

ESPACE-WORLD

This CD-ROM product contains the complete PCT patent applications published since 1991. Each is stored in facsimile format with searchable biographical information and titles.

ESPACE-ACCESS

This CD-ROM product contains EPO patent applications published since 1978. Each is stored in image form with bibliographic information on the title page index coded for searching. Searchable English language abstracts are progressively being introduced.

ESPACE-UK

This CD-ROM product contains bibliographic data (searchable) and complete facsimile images of United Kingdom patent applications (A-documents) published since 1990.

CD-ROM products of the Japan Patent Information Organization:

JAPIO

This CD-ROM product contains the full text images of unexamined Japanese patent and utility model applications published since 1987, including bibliographic information. It is in Japanese.

CD-ROM products of the United States Patent and Trademark Office:

CASSIS/BIB

This CD-ROM product contains the U.S. classifications, assignees, titles, abstracts (most recent three years only) and patent origin (residence state or country of first named inventor) for U.S. patents issued since 1969.

*CD-ROM products of MicroPatent:**ClaimSearch*

This CD-ROM product contains the full text of all claims for patents issued by the USPTO since 1975 together with bibliographic information.

FullText This CD-ROM product contains the full text of patents issued by the USPTO since 1975. Patents can be retrieved by patent number only.

PatentImages

This CD-ROM product contains the full-text images of U.S. patents including drawings for patents issued by the USPTO since 1990, with backfiles to 1976 available during 1992.

*Addresses and telephone numbers for the selected sources:**European Patent Office*

Principal Directorate, Patent Information, European Patent Office, EPIDOS-INPADOC Services, Schottenfeldgasse 29, Postfach 82/ P.O. Box 82, A-1072 Vienna, Austria. (From January 20, 1992). Telephone: 43-1-52126-0; FAX: 43-1-52126-1493.

Japanese Patent Information Organization

Japan Patent Information Organization, International Department, Sato-Dia Bldg.; 1-7 Toyo 4-chome, Kotu-Ku, Tokyo 135, Japan. Telephone: 81-3-5690-5555; FAX: 81-3-5690-5566.

United States Patent and Trademark Office

U.S. Patent and Trademark Office, Office of Electronic Information Products and Services, Crystal Mall 2, Room 304, Washington, D.C. 20231, U.S.A. Telephone: 1-703-557-5652.

MicroPatent

MicroPatent Canada - Micromedia Limitee, Mr. Gary Gibson, 265 Hotel de Ville, Hull, Quebec J8X. Telephone: 800-567-1914; FAX: 819-770-9265

MicroPatent Europe, Ms. Elisabeth Hearle, Cambridge Place, Cambridge CB2 1NR, England. Telephone: 44-223-311-479; FAX: 44-223-66440

MicroPatent France - Chadwyck-Healey France, 3, rue de Marivaux, 75002 Paris. Telephone: 33-42-86-80-20; FAX: 33-42-61-33-87

MicroPatent Mexico - Diffusion Cientifica Latinoamericana S.A., Glorieta de Claveria, Mexico, 08020 DF. Telephone: 52-5-396-1818; FAX: 52-5-341-3647

MicroPatent USA, 25 Science Park, New Haven, CT 06511. Telephone: 1-203-786-5500; FAX: 1-203-786-5499.

CASE NOTES

Computer Associates v. Altai and *Apple v. Microsoft*: Two Steps Back From *Whelan*?

Computer Associates International, Inc. v. Altai, Inc., 23 U.S.P.Q.2d (BNA) 1241, (2d Cir. 1992). *Apple Computer, Inc. v. Microsoft Corp.*, 799 F.Supp. 1006, (N.D. Cal. 1992).

Audrey F. Dickey*

In 1986, the Third Circuit, in *Whelan Associates v. Jaslow Dental Laboratory*,¹ defined a test for copyright infringement of computer programs that went beyond simply looking for literal copying of the elements. The court laid the foundation for what has become known as the "look and feel" analysis to determine substantial similarity by comparing not only the literal elements, but the sequence, structure and organization of a program. Since *Whelan*, many courts have used a similar analysis for determining copyright infringement of software, but in the summer of 1992, two cases were decided that may mark the beginning of a retreat from the "look and feel" doctrine, and may have a significant impact on the future of computer program copyright actions. These cases are *Computer Associates International, Inc. v. Altai, Inc.*,² a Second Circuit case, and *Apple Computer, Inc. v. Microsoft Corp.*³ from the Northern District of California.⁴ Both cases criticized the approach in *Whelan* and bring forth the question as to whether similarity in structure will continue to be sufficient to show copyright infringement in computer software.

The courts began their analysis in both cases by looking at the two elements needed to show infringement, access and substantial similarity. In both cases, access was available and so the question hinged on whether there was substantial similarity. In neither case

Copyright © 1993 by Audrey F. Dickey.

* B.A. University of Michigan; M.B.A. Santa Clara University Leavey School of Business and Administration; Candidate J.D. 1993 Santa Clara University School of Law.

1. 787 F.2d 1222.

2. 23 U.S.P.Q. (BNA) 1241 (2d Cir. 1992).

3. 799 F.Supp. 1006 (N.D. Cal. 1992).

4. Coincidentally, both decisions were written by a Judge Walker. John M. Walker, Jr. in the *Computer Associates* case, and Vaughn Walker in *Apple v. Microsoft*.

was there literal copying of the elements. Although the analyses used by the two judges appeared to be different, there were fundamental similarities in the treatment of the programs, looking at them not as whole works, but at their component parts to determine similarity. The results were also similar. In *Computer Associates*, no infringement was found. In *Apple v. Microsoft*, summary judgment was granted on 300 out of 304 alleged violations, with only four elements found to be possible protected expression.

The facts of *Computer Associates* were outlined in the District court decision.⁵ Computer Associates (CA) wrote a job-scheduling program called CA-Scheduler for the IBM System 370 family of computers. IBM sells three different operating systems for this family, and software developers who want their programs to run on all three must usually write three different versions in order to be consistent with whatever operating system the customer might choose. To avoid the burden of writing three versions of CA-SCHEDULER, CA wrote one version, consisting of two parts. One part, called SCHEDULER, performed the actual job scheduling functions. When it needed to communicate with the operating system, it passed control to the second part, ADAPTER. ADAPTER provided the proper interface between SCHEDULER and the operating system and was able to communicate with any of the three operating systems, translating the commands from SCHEDULER to the proper format for the operating system in use. ADAPTER was used not only in CA-SCHEDULER, but in other programs written by CA. ADAPTER was not sold separately.

Altai attempted to market a program similar to CA-SCHEDULER, but Altai's version was not as versatile. Their first attempt, called ZEKE, did not have the equivalent of an ADAPTER module, but was only able to run on one IBM operating system. Subsequently, Altai developed Oscar, their version of ADAPTER. The first version of OSCAR, OSCAR 3.4, was written by a former employee of CA and, it was later discovered, contained much code that was copied directly from ADAPTER. Once it was revealed to Altai's management that OSCAR was a possible infringement on CA's program, they began efforts to rewrite OSCAR in order to eliminate all of the copied code. It is this second version of OSCAR, OSCAR 3.5, that is in question in this case. The argument hinged on whether Altai's OSCAR 3.5 was substantially similar to CA's program. CA claimed that despite the rewrite of OSCAR, it was still substantially the same as ADAPTER. In the

5. *Computer Associates Int'l. v. Altai, Inc.*, 775 F.Supp. 544, 549-53 (E.D.N.Y. 1991).

decision, the court agreed with *Whelan* that copyright infringement can go beyond just literal copying.⁶ But the court went on to say that this did not end the analysis. Rather, the next step was to determine the extent of the protection for non-literal structure.

Judge Walker then discussed the problem inherent in the idea-expression dichotomy and the even greater difficulty in separating the two in computer programs. *Whelan* was cited for its attempt to draw the line between idea and expression, but Judge Walker then criticized the *Whelan* concept of a single idea defining a program. In the *Whelan* analysis, once the idea of the program is determined, the program itself provides the expression of that idea. Judge Walker saw this as the fatal flaw in the *Whelan* reasoning, the assumption that only one idea could underlie any computer program. According to Judge Walker, a program can contain many sub-programs, each with its own idea.⁷ Judge Walker then explained the Second Circuit approach to determining substantial similarity, the Abstraction-Filtration-Comparison test. This is a three-part test that starts with the abstractions test first expounded by Learned Hand in *Nichols v. Universal Pictures*.⁸ The program is broken down into levels of abstraction from the most complex, a collection of instructions, to the simplest, the ultimate function of the program. After the levels are identified, then the filtering test takes place. Each component at each level is examined to determine whether or not the component is protectible expression. It could be that the module contains an idea rather than expression. If the module is expression, that expression may be dictated by considerations of efficiency, required by factors external to the program, or taken from the public domain. Any of these reasons would cause that component to be non-protectible.

Once the elements deemed non-protectible in the filtration process have been sifted out, the remainder represents the "core of protected expression."⁹ At this point, the court must determine if the defendant copied any aspect of this expression. But another part of the analysis focuses on the copied portion's relative importance to the overall program. Thus, even if substantial similarity is found, it may be that the similar piece is determined to be of such relatively little importance to the overall work that no infringement would be found. Judge Walker defended his approach as one that "not only

6. *Computer Associates*, 23 U.S.P.Q. (BNA) 1241, 1249.

7. *Id.* at 1252.

8. 45 F.2d 119 (2nd Cir. 1930).

9. *Computer Associates*, 23 U.S.P.Q. (BNA) 1241, 1256.

comports with, but advances the constitutional policies underlying the copyright act."¹⁰ He emphasized that the primary objective of the copyright law is to stimulate creativity, not reward authors. He criticized the *Whelan* rationale as too sweeping because it allows the first to implement certain techniques to put a "lock" on them, resulting in an inhibition of creation. He also stated his belief that copyright is not the most suitable method of protection for computer software and that the result of the decision in this case flowed from Congressional intent, rather than the most effective way to protect computer software.¹¹

In applying his test to the instant case, Judge Walker looked at each level of abstraction in the alleged infringed program, ADAPTER. The levels of abstraction that he found were object code, source code, parameter lists and macros, services required, and the general outline. At the code levels, he found no similarity at all, since the code had been rewritten to remove the identical code. On the level of parameter lists and macros, there were elements that were similar to protected elements, but they were deemed insignificant compared to the overall program. The list of services required were found to be determined by the demands of the operating system, and the organizational charts were considered to be simple and obvious, following naturally from the work's theme.¹² Thus, no infringement was found.

Apple's suit against Microsoft and Hewlett-Packard (HP) involved the immensely successful Windows software by Microsoft, which sits on the DOS¹³ operating system and extends its visual and graphical capabilities. Apple also uses a graphical interface for its Macintosh line of computers. In 1985, in an attempt to put to rest arguments as to whether Windows infringed on Apple's copyright for its Macintosh operating system, Apple granted to Microsoft a non-exclusive license for the audiovisual displays in the first version of Windows, Windows 1.0. In turn, Microsoft had given HP a license for some of the displays used in Windows that HP had incorporated into their software called NewWave. However, these licenses covered only the displays found in Windows 1.0 and did not cover those that first appeared in a subsequent release, Windows 2.03. Apple filed suit against Microsoft and HP for infringing on

10. *Id.*

11. *Id.* at 1257.

12. *Id.* at 1260.

13. This is a Microsoft trademarked acronym for Disc Operating System.

those copyrights of elements not covered by the 1985 agreement.¹⁴ Apple attempted to base its suit on the similarity of the overall look of Windows and NewWave to the Apple Macintosh graphical interface which Apple later described as a "desk-top metaphor."¹⁵ In 1985, the court did not accept Apple's "look and feel" argument and requested that Apple submit a list of the alleged similarities between the Macintosh displays the Windows and NewWave. Apple's list contained 189 alleged similarities between the Apple works and Windows and 147 similarities between the Apple displays and NewWave.¹⁶ Microsoft and HP filed motions for summary judgment, claiming no infringement on a variety of grounds. The court determined that 179 of the similarities claimed in Windows¹⁷ and 135 in NewWave¹⁸ were covered by the 1985 license. A subsequent decision determined that the ten remaining items relating to Windows and 53 out of 54 of the NewWave items were subject to little or no copyright protection and summary judgment was granted to Microsoft and HP on those 63 items.¹⁹ Apple moved for reconsideration and this decision is the result of that reconsideration. In this case, Judge Walker used the two-part test of the Ninth Circuit for determining copyright infringement. This test starts with an extrinsic, or objective, analysis of the work using expert testimony to determine criteria for comparison.²⁰ During this stage of the analysis not only is similarity of ideas determined, but the elements that can be protected by copyright must be identified. This is similar to the filtering step used by Judge John Walker in the *Computer Associates* decision. Once the protectible elements are determined, an "intrinsic test" or "subjective analysis of expression"²¹ is used. This part of the test is performed not by the court, but by the trier of fact. However, should the extrinsic analysis result in no protectible elements of the work, then the intrinsic test is unnecessary and summary judgment is appropriate.²²

Judge Walker then went on to describe the doctrines that would cause an element to be deemed unprotectible, that is, merger,

14. *Apple Computer, Inc. v. Microsoft Corp.*, 709 F.Supp. 925, 930 (N.D. Cal. 1989).

15. *Apple Computer, Inc. v. Microsoft Corp.*, 799 F.Supp. 1006 (N.D. Cal. 1992).

16. *Id.* at 1016.

17. *Apple Computer, Inc. v. Microsoft Corp.*, 717 F.Supp. 1428 (N.D. Cal. 1989).

18. *Apple Computer, Inc. v. Microsoft Corp.*, 759 F.Supp. 1444 (N.D. Cal. 1991).

19. *Apple Computer, Inc. v. Microsoft Corp.*, 1992 WL 75423 (N.D. Cal. 1992).

20. *See Sid & Marty Krofft Television v. McDonald's Corp.*, 562 F.2d 1157, 1164 (9th Cir. 1977); *Shaw v. Lindheim*, 919 F.2d 1353, 1357 (9th Cir. 1990).

21. *Shaw*, 919 F.2d at 1357.

22. *Apple Computer, Inc. v. Microsoft Corp.*, 799 F.Supp. 1006, 1020 (N.D. Cal. 1992).

indispensable expression (*scenes a faire*), idea rather than expression, and lack of originality. According to Judge Walker, courts have developed these limiting doctrines as a response to the problem of balancing between the revenue and cost effects inherent in copyright protection. Although copyright affords an incentive to authors by allowing them to recoup their investment in creativity, it also increases the costs of creation by keeping that creative work the exclusive property of one author.²³

Apple argued that in order to understand the appearance of the Macintosh interface one must look not only at the individual elements, but the way those elements interact with one another. Thus, the "look and feel" doctrine could be used to compare the overall appearance of the Macintosh with Windows and NewWave. However, Judge Walker rejected this argument, saying that the desktop metaphor was not the idea unifying the expressive elements, but rather merely "a collection of visual displays and user commands designed to render use of the computer . . . more utilitarian."²⁴ He saw the elements as performing a purely functional purpose, and likened the display and commands to the various parts of an automobile. No copyright protection is available for utilitarian articles.²⁵

The court then went on to criticize the *Whelan* court for its formulation that a program's overall purpose constitutes the idea and that the program itself is the expression of that idea. According to the law of the Ninth Circuit, a program can contain many ideas. Judge Walker also pointed to the 1985 agreement as proof that Apple and Microsoft accepted the individual displays as the protectible expression, not the totality of the programs.²⁶ Having explained his approach to the problem, Judge Walker then proceeded to analyze each of the displays in question. He had granted summary judgment to Microsoft on its claims of non-infringement for all ten remaining items in his previous decision. In this reconsideration, he affirmed his previous decision on all items. Previously HP was granted summary judgment for all but one claim, the trash can icon.

In the instant decision, Judge Walker reconsidered and changed his decision of three items dealing with the appearance of icons as windows are opening and closing, as well as reaffirming the

23. *Id.* at 1021.

24. *Id.* at 1023.

25. *Id.*

26. *Id.* at 1025.

protectibility of the trash can icon.²⁷ In determining the protectibility or non-protectibility of the elements in question, Judge Walker used the limiting doctrines mentioned above. Microsoft and HP were able to show that before and during the development of Lisa, the predecessor to the Macintosh, the Apple development engineers were exposed to other graphical interface systems, and that Apple incorporated into their products some of the ideas that they obtained from observing these other systems. The defendants also showed that the other graphical user interfaces on the market always incorporate the basic elements of the Macintosh interface. Due to these two arguments, many of the contested elements were found to be non-protectible because of either lack of originality or indispensable expression. In addition, some elements were found to contain not expression but ideas.

In both cases, the courts were critical of the *Whelan* approach which treats a program as the expression of a single idea. The courts in these two decisions also used similar methods of breaking the program down into many elements and "filtering out" non-protectible elements, making a case for "look and feel" much more difficult to support. The role of sequence, structure and organization, the foundation of the "look and feel" doctrine, played little or no part in the analysis by concentrating on the parts rather than the whole.

However, one should not draw a conclusion from these cases that "look and feel" is dead. In each case, unique factors existed that may not be present in other software copyright cases. In *Computer Associates*, the program's function was narrowly defined by the application. Judge John Walker based much of his decision on non-protectibility on the reason that the element was required by factors external to the program. It has been well known in the industry that Apple's development engineers acquired many of their ideas for the Lisa, the forerunner of the Macintosh, from systems that they saw at Xerox. It was not surprising, then, that Judge Vaughn Walker leaned heavily on the limiting doctrine of lack of originality in reaching his decision. Should the next software case contain none of these unique factors, it may be that the decision will heartily support the *Whelan* approach. We will have to wait and see.

Judge John Walker, in discussing the policy considerations leading to his decision, described his dilemma as follows:

27. *Apple*, 799 F.Supp. at 1042.

To be frank, the exact contours of copyright protection for non-literal program structure are not completely clear. We trust that as future cases are decided, those limits will become better defined. . . Generally, we think that copyright registration — with its indiscriminating availability — is not ideally suited to deal with the highly dynamic technology of computer science. Thus far, many of the decision in this area reflect the courts' attempt to fit the proverbial square peg in a round hole.²⁸

The law of software copyright is constantly changing. These two decisions could be two steps in a totally different direction, or they could be merely a detour along the road we have been following for six years. Only time and the courts will tell.

28. *Computer Associates*, at 1257.

IS AN INHERENTLY DISTINCTIVE TRADE DRESS
PROTECTABLE UNDER § 43(A) WITHOUT HAVING
ACQUIRED A SECONDARY MEANING? *Two Pesos, Inc. v.
Taco Cabana, Inc.*, 112 S.Ct. 2753 (1992), *rehearing denied*,
113 S.Ct. 20 (1992).

Fariba Soroosh*

INTRODUCTION

On June 26, 1992, the Supreme Court unanimously held that inherently distinctive trade dress¹ is protectable under Section 43(a)² of the Lanham Act³ [hereinafter the Act], without a showing that it has acquired a secondary meaning.⁴ In affirming the Fifth Circuit's decision, the High Court followed that Circuit's reasoning that trade dress should be protected by the same principles applicable to trademarks because they both serve "the same statutory pur-

Copyright © 1993 by Fariba Soroosh.

* Ms. Soroosh holds a B.S. in Business Management from San Jose State University and a J.D. from Santa Clara University School of Law.

1. In defining trade dress, the Court adopted the Fifth and Eleventh Circuits' definitions. The Fifth Circuit "quoted from *Blue Bell Bio-Medical v. Cin-Bad, Inc.*, 864 F.2d 1253, 1256 (5th Cir. 1989): 'The "trade dress" of a product is essentially its total image and overall appearance.' *Id.* See [*Taco Cabana Int'l, Inc. v. Two Pesos, Inc.*], 932 F.2d 1113, 1118 (5th Cir. 1991)." *Two Pesos, Inc. v. Taco Cabana, Inc.*, 112 S.Ct. 2753, 2755 n.1 (1992), *rehearing denied*, 113 S.Ct. 20 (1992).

The Eleventh Circuit has stated that trade dress "involves the total image of a product and may include features such as size, shape, color or color combinations, texture, graphics, or even particular sales techniques" (quoting *John H. Harland Co. v. Clarke Checks, Inc.*, 711 F.2d 966, 980 (11th Cir. 1983)). *Id.*

2. 15 U.S.C. § 1125(a) (1982). The Court considered the version of the code prior to the 1988 amendments. It provides:

Any person who shall affix, apply, or annex, or use in connection with any goods or services, or any container or containers for goods, a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent the same, and shall cause such goods or services to enter into commerce, and any person who shall with knowledge of the falsity of such designation of origin or description or representation cause or procure the same to be transported or used in commerce or deliver the same to any carrier to be transported or used, shall be liable to a civil action by any person doing business in the locality falsely indicated as that of origin or in the region in which said locality is situated, or by any person who believes that he is or is likely to be damaged by the use of any such false description or representation.

Two Pesos, 112 S.Ct. at 2761 n.1 (quoting 15 U.S.C. § 1125(a) (1982 ed.)).

3. 15 U.S.C. §§ 1051-1127 (1982).

4. *Two Pesos*, 112 S.Ct. at 2753.

pose of preventing deception and unfair competition."⁵ Justice Byron White wrote the opinion joined by six other members of the Court, Justices Stevens and Thomas filed separate concurring opinions, and Justice Scalia concurred with the majority and with Justice Thomas's opinion.

The holding in this case, granting trade dress protection to the particular motif of a restaurant chain, is significant for several reasons. First, the Court resolved a conflict among the Courts of Appeals and determined that § 43(a) does not impose a blanket secondary meaning requirement for trade dress protection. This case sets forth the rule that a distinctive trade dress should get the same treatment as a distinctive trademark under § 43(a). Hence, protection is granted when a particular mark or dress is either inherently distinctive⁶ or has become sufficiently distinctive through acquiring a secondary meaning⁷.

Second, the Court declared that the Fifth Circuit had been correct in applying trademark analysis to trade dress, because there is no textual basis for treating the two differently. The protection of both is necessary in achieving legislative purposes behind the Lanham Act.⁸

Finally, the Court rejected petitioner's argument that a new inherently distinctive dress that has not attained a secondary meaning be given temporary protection, to be terminated if a secondary meaning is not achieved over time. The Court reasoned that if a trade dress is granted protection in the first place without having a secondary meaning, then it must be inherently distinctive and capable of identifying its source. Such a dress deserves continued protection without regard to its ability to succeed in the market and attain a secondary meaning.

BACKGROUND

Taco Cabana, respondent, opened its first restaurant in San Antonio, Texas, in 1978. Customer response to this Mexican res-

5. *Id.* at 2755.

6. An inherently distinctive trade dress is capable of identifying a product or service's source because of its intrinsic nature. *Id.* at 2757.

7. "Secondary meaning is used generally to indicate that a mark or dress 'has come through use to be uniquely associated with a specific source.'" *Id.* at 2756 n.4 (quoting RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 13, Cmt. e (Tentative Draft No. 2, 1990)).

8. *Two Pesos, Inc. v. Taco Cabana, Inc.*, 112 S.Ct. 2753, 2755 (1992), *rehearing denied*, 113 S.Ct. 20 (1992).

taurant with its festive motif⁹ was so favorable that by 1985, respondent had opened five more restaurants in the San Antonio area.

Two Pesos, petitioner, opened its first restaurant in December 1985, in Houston. Petitioner's atmosphere and decor were very similar to that of the respondent. Petitioner expanded rapidly in Houston and other Texas cities, but did not enter the San Antonio area. In 1986, respondent started to expand into other markets, including Austin, Dallas, El Paso and Houston, where petitioner was also doing business.

In 1987, respondent sued petitioner in the United States District Court for the Southern District of Texas¹⁰ for trade dress infringement under § 43(a), and for theft of trade secrets under the Texas common law¹¹. Respondent claimed that it had a trade dress that was protectable under § 43(a) from its inception, "i.e., an elaborate, consistently maintained combination of structural and decor elements that give it a consistent look."¹²

A jury trial ensued, in which the jury was instructed to return its verdict in the form of answers to five questions. "The jury's answers were: Taco Cabana has a trade dress;¹³ taken as a whole, the trade dress is non-functional;¹⁴ the trade dress is inherently distinc-

-
9. The respondent described its Mexican trade dress as a festive eating atmosphere having interior dining and patio areas decorated with artifacts, bright colors, paintings and murals. The patio includes interior and exterior areas with the interior patio capable of being sealed off from the outside patio by overhead garage doors. The stepped exterior of the building is a festive and vivid color scheme using top border paint and neon stripes. Bright awnings and umbrellas continue the theme.

Id.

10. *Taco Cabana International, Inc. and Taco Cabana, Inc. v. Two Pesos, Inc.*, No. H-87-0026, 1988 U.S. Dist. LEXIS 16068 (S.D. Texas 1988).

11. On this issue the jury concluded that Two Pesos had misappropriated Taco Cabana's trade secrets, and the Fifth Circuit affirmed. *Taco Cabana Int'l, Inc. v. Two Pesos, Inc.*, 932 F.2d at 1124. Petitioner did not appeal this decision.

12. *Briefs Are Filed in Mexican Restaurant Trade Dress Case*, PAT. TRADEMARK & COPYRIGHT J. (BNA), No. 1077, at 523 (April 16, 1992).

13. The District Court instructed the jury: "'Trade dress' is the total image of the business. Taco Cabana's trade dress may include the shape and general appearance of the exterior of the restaurant, the identifying sign, the interior kitchen floor plan, the decor, the menu, the equipment used to serve food, the servers' uniforms and other features reflecting on the total image of the restaurant.'" *Two Pesos, Inc. v. Taco Cabana, Inc.*, 112 S.Ct. 2753, 2754 n.1 (1992).

14. Respondent's dress would be functional if, as a whole, it was essential to the very nature of being a Mexican restaurant. "The Fifth Circuit holds that a design is legally functional, and thus unprotectable, if it is one of a limited number of equally efficient options available to competitors and free competition would be unduly hindered by according the design trademark protection." *Id.* at 2760 (citing *Sicilia Di R. Biebow & Co. v. Cox*, 732 F.2d 417, 429 (5th Cir. 1984)).

tive; the trade dress has not acquired a secondary meaning in the Texas market; and the alleged infringement creates a likelihood of confusion on the part of ordinary customers as to the source or association of the restaurant's goods or services."¹⁵ Since the jury was instructed that Taco Cabana's trade dress would be protectable if it had either acquired a secondary meaning or was inherently distinctive, judgment was entered for Taco Cabana. The trial court awarded Taco Cabana \$2.8 million in damages¹⁶, and "held that Two Pesos had intentionally and deliberately infringed Taco Cabana's trade dress."¹⁷

On appeal, petitioner argued that the jury's finding of no secondary meaning contradicted their finding of inherent distinctiveness.¹⁸ According to petitioner, what Taco Cabana had was a broad and functional business concept which did not come under the limited protection of trade dress.¹⁹ Petitioner further argued that if such a concept is granted trade dress protection, it should only be for a limited time.²⁰ If no secondary meaning is attained during this time, protection should cease and aggressive competitors should be allowed to expand in the market using the same business concept.²¹ The Fifth Circuit rejected petitioner's argument, and affirmed the District Court's judgment.

The Fifth Circuit specifically noted that their approach in this case was in conflict with the Second Circuit.²² The Supreme Court granted certiorari "to resolve a conflict among the Courts of Appeals on the question of whether trade dress which is inherently distinctive is protectable under § 43(a) without a showing that it has acquired secondary meaning."²³

15. *Two Pesos*, at 2756. In deciding this case, the Supreme Court assumed that the jury was correct in their findings. *Id.* at 2758.

16. *Taco Cabana Int'l, Inc. v. Two Pesos, Inc.*, 932 F.2d 1113, 1117 (5th Cir. 1991). In calculating this figure, the District Court doubled the damages award and granted attorney's fees. See *Inherently Distinctive Trade Dress Is Protectable Without Secondary Meaning*, PAT. TRADEMARK & COPYRIGHT J. (BNA), No. 1088, at 213 (July 2, 1992).

17. *Two Pesos*, 112 S.Ct. at 2756. The Fifth Circuit agreed with this holding stating that "[t]he weight of the evidence persuades us. . . that Two Pesos brazenly copied Taco Cabana's successful trade dress, and proceeded to expand in a manner that foreclosed several important markets within Taco Cabana's natural zone of expansion." *Id.* 2756 at n.5 (quoting *Two Pesos*, 932 F.2d at 1127 n.20). This holding seems to have only affected the amount of damages awarded to respondent, and did not have any bearing on the High Court's analysis and holding.

18. *Two Pesos*, 112 S.Ct. at 2754.

19. See *Briefs Filed in Mexican Restaurant Trade Dress Case*, *supra* note 12.

20. *Two Pesos*, 112 S.Ct. at 2754.

21. *Id.*

22. *Id.* at 2756.

23. *Id.* at 2757 (citing 112 S.Ct. 964 (1992)). The Court noted that certiorari was not

DISCUSSION

The Second Circuit Approach Rejected

In *Vibrant Sales, Inc. v. New Body Boutique, Inc.*²⁴, the Second Circuit held that “§ 43(a) protects unregistered trademarks or designs only where secondary meaning is shown.”²⁵ That Court did not adopt the view that an “unregistered mark was capable of identifying a source and that copying such a mark could be making any kind of false statement or representation under § 43(a).”²⁶ The rationale underlying their decision was that “unregistered marks did not enjoy the presumptive source association enjoyed by registered marks and hence could not qualify for protection under § 43(a) without proof of secondary meaning.”²⁷ Although this Circuit later altered its position and waived the secondary meaning requirement for nondescriptive suggestive marks²⁸, they have continued to impose such a requirement on trade dress under § 43(a).²⁹

The Supreme Court rejected this approach because, as Justice White noted, it was “in considerable tension with the provisions of the Act.”³⁰ The Court reasoned that since section 2³¹ of the Act, which sets out trademark registrability requirements only requires a secondary meaning for descriptive marks, there must be marks

being granted “on the second question presented by the petition, which challenged the Court of Appeals’ acceptance of the jury’s finding that Taco Cabana’s trade dress was not functional.” *Id.* at 2757 n.6.

24. 652 F.2d 299 (2d Cir. 1981), *cert. denied*, 455 U.S. 909 (1982).

25. *Two Pesos, Inc. v. Taco Cabana, Inc.*, 112 S.Ct. 2753, 2756 (1992) (citing *Chevron Chemical Co. v. Voluntary Purchasing Groups, Inc.*, 659 F.2d 695 (5th Cir. 1981)).

26. *Id.* at 2759.

27. *Id.* (citing *Vibrant Sales, Inc. v. New Body Boutique, Inc.*, 652 F.2d 299, 303 (2d Cir. 1981)).

28. *Thompson Medical Co. v. Pfizer, Inc.*, 753 F.2d 208 (2d Cir. 1985).

29. *Two Pesos*, 112 S.Ct. at 2759-60.

30. *Id.* at 2759.

31. 15 U.S.C. § 1052. This section sets out circumstances under which a trademark would not be registrable. Only two subsections are at issue in this case:

No Trade mark by which the goods of the applicant may be distinguished from the goods of others shall be refused registration on the principal register on account of its nature unless it

(e) Consists of a mark which, (1) when used on or in connection with the goods of the applicant is merely descriptive or deceptively misdescriptive of them, or (2) when used on or in connection with the goods of the applicant is primarily geographically descriptive or deceptively misdescriptive of them, except as indications of regional origin may be registrable under section 1054 of this title, or (3) is primarily merely a surname.

(f) Except as expressly excluded in paragraphs (a)-(d) of this section, nothing in this chapter shall prevent the registration of a mark used by the applicant which has become distinctive of the applicant’s goods in commerce. . . .

15 U.S.C. § 1052 (1992).

(such as distinctive ones) that qualify without having a secondary meaning.³² The Court also stated that "These same marks, even if not registered, remain inherently capable of distinguishing the goods of the users of these marks."³³

The Court found support in other Circuits that follow the approach used by the Fifth Circuit. The Ninth Circuit, for example, has held that if the dress is inherently distinctive, proof of secondary meaning is then needless.³⁴

Fifth Circuit Approach Adopted

In affirming the Fifth Circuit's judgment, the High Court approved of, and adopted, that Circuit's approach to trade dress protection under § 43(a). "The Fifth Circuit was quite right in *Chevron*³⁵, and in this case, to follow the *Abercrombie* classifications³⁶ consistently and to inquire whether trade dress for which protection is claimed under § 43(a) is inherently distinctive."³⁷

The analysis is therefore two fold; first, the mark or dress has to qualify for registration³⁸ under § 2 of the Act; and second, it has to be examined under § 43(a) for non-functionality and likelihood of confusion.³⁹ The second step is straight forward, the first one deserves a detailed discussion.

In *Abercrombie & Fitch Co. v. Hunting World, Inc.*⁴⁰, Judge Friendly set out what was to become the traditional trademark reg-

32. *Two Pesos*, 112 S.Ct. at 2759.

33. *Id.*, see 15 U.S.C. § 1052(f) *supra* note 31.

34. *Two Pesos*, 112 S.Ct. at 2760 (citing *Fuddruckers, Inc. v. Doc's B.R. Others, Inc.*, 826 F.2d 837, 843 (9th Cir. 1987)). See also *Ambrit, Inc. v. Kraft, Inc.*, 805 F.2d 974 (11th Cir. 1986) (The Eleventh Circuit followed the Fifth Circuit approach in *Chevron*, *infra* note 35); *Excerpts From The United States Trademark Association's Amicus Brief in Two Pesos*. . . , 82 THE TRADEMARK REPORTER 440 (May-June 1992) (the United States Trademark Association supports the Fifth Circuit's position that inherently distinctive trade dress may be protected without proof of secondary meaning).

35. *Chevron Chemical Co. v. Voluntary Purchasing Groups, Inc.*, 659 F.2d 695 (5th Cir. 1981).

36. See discussion *infra* pp. 10-12.

37. *Two Pesos*, 112 S.Ct. at 2760.

38. The Court stated that actual registration is not required for protection under § 43(a). They reaffirmed the position taken earlier in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982), that § 43(a) "prohibits a broader range of practices than does § 32 [15 U.S.C. § 1114], which is applied to registered trademarks. . . ." *Two Pesos*, 112 S.Ct. at 2757 (quoting *Inwood*, *supra* at 858). The Court went on to say that "it is common ground that § 43(a) protects qualifying unregistered trademarks and that the general principles qualifying a mark for registration under § 2 of the Lanham Act are for the most part applicable in determining whether an unregistered mark is entitled to protection under § 43(a)." *Two Pesos*, 112 S.Ct. at 2757.

39. *Two Pesos*, 112 S.Ct. at 2758.

40. 537 F.2d 4 (2d Cir. 1976).

istrability analysis under § 2. According to this classic formulation, trademarks are usually classified in categories of increasing distinctiveness.⁴¹ “[T]hey may be (1) generic; (2) descriptive; (3) suggestive; (4) arbitrary; or (5) fanciful.”⁴² The latter three categories are entitled to registration because they are inherently distinctive, that is, “their intrinsic nature serves to identify a particular source of a product.”⁴³ Conversely, marks that “refer to the genus of which the particular product is a species,” or generic marks, are not registerable.⁴⁴ In between these two extremes, there exists the descriptive mark category, into which the respondent’s dress fell.

Pursuant to § 2(e) of the Lanham Act, purely descriptive marks are not registerable because they do not identify the particular source, but merely describe the product.⁴⁵ However, § 2(f) of the Act provides that descriptive marks that have “become distinctive of the applicant’s goods in commerce” are registerable.⁴⁶ The Supreme Court in *Taco Pesos*, in harmony with the Fifth Circuit, held that this general rule, usually applicable only to trademarks, should also be applied to trade dress protection cases.⁴⁷ Justice White cited the most recent definition of distinctiveness as “an identifying mark [that] either (1) is inherently distinctive or (2) has acquired distinctiveness through secondary meaning.”⁴⁸

The Court reasoned that an inherently distinctive trade dress is also capable of identifying its source,⁴⁹ and that “the protection of trade dress serves the same statutory purpose of preventing deception and unfair competition.”⁵⁰ Furthermore, the Court considered it important that there was no textual basis in § 43(a) either mentioning the concept of secondary meaning, or supporting the different treatment of marks and dresses.⁵¹ The only specific requirements for protection under this section, and the second part of the analysis, is establishing non-functionality and lack of likelihood of confusion among consumers.⁵² Additionally, the Court foresaw

41. *Two Pesos*, 112 S.Ct. at 2757 (citing *Abercrombie & Fitch* 537 F.2d 4).

42. *Two Pesos*, 112 S.Ct. at 2757.

43. *Id.*

44. *Id.* (quoting *Park’N Fly, Inc. v. Dollar Park and Fly, Inc.*, 469 U.S. 189, 194 (1985)).

45. *Id.*

46. 15 U.S.C. § 1052(f), *supra* note 31.

47. *Two Pesos*, 112 S.Ct. at 2760.

48. *Id.* at 2758 (quoting RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 13, pp. 37-38, and comment a (Tent.Draft No. 2, Mar. 23, 1990)).

49. *Id.* at 2754.

50. *Id.* at 2760.

51. *Id.*

52. *Id.* at 2758.

the adverse effects of imposing a blanket secondary meaning requirement on all inherently distinctive trade dress, and was extremely concerned about its anti-competitive effects.

The Court disfavored imposing such a requirement because it would be contradictory to the free enterprise ideology that underlaid the Constitutional basis of trademark protection. It would also undermine the legislative intent behind the Act. In regard to this, the court stated:

Protection of trade dress, no less than of trademarks, serves the Act's purpose to secure the owner of the mark the goodwill of his business and to protect the ability of consumers to distinguish among competing producers. National protection of trademarks is desirable, Congress concluded, because trademarks foster competition and the maintenance of quality by securing to the producer the benefits of good reputation.⁵³ By making more difficult the identification of a producer with its product, a secondary meaning requirement for a nondescriptive trade dress would hinder improving or maintaining the producer's competitive position.⁵⁴

Petitioner's Limited Protection Argument Rejected

The Court rejected petitioner's proposal that a distinctive trade dress be granted temporary protection at the outset subject to termination if secondary meaning is not attained over time. The Court held that there was no textual basis in § 43(a) for this concept. Using the Fifth Circuit's reasoning, the Supreme Court stated that "[i]f temporary protection is available from the earliest use of the trade dress, it must be because it is neither functional nor descriptive but an inherently distinctive dress that is capable of identifying a particular source of the product."⁵⁵ The Court felt that lack of market success and consumer recognition over an unspecified period of time were not valid bases for discontinuing protection.⁵⁶ "The user of such a trade dress should be able to maintain what competitive position it has and continue to seek wider identification among potential consumers."⁵⁷

Some analysts see this holding as a sign that the Supreme

53. *Id.* at 2760 (quoting *Park'N Fly, Inc. v. Dollar Park and Fly, Inc.*, 469 U.S. 189, 198 (1985)).

54. *Two Pesos, Inc. v. Taco Cabana, Inc.*, 112 S.Ct. 2753, 2760 (1992), *rehearing denied*, 113 S.Ct. 20 (1992).

55. *Id.* at 2759.

56. *Id.*

57. *Id.*

Court recognized the doctrine of "secondary meaning in the making."⁵⁸ This doctrine aims at protecting an inherently distinctive trade dress that has not yet been identified by the public as belonging to a certain proprietor. Hence, trade dress originators would have the chance to build up their reputation and compete in new markets, while being protected against imitators who would deter competition and expansion. The Court believed that an opposite holding would discourage start-up companies from entering the market, knowing that their original, nonfunctional and inherently distinctive trade dress would not be protected absent enough consumer recognition for a secondary meaning.⁵⁹

CONCURRING OPINIONS

Justice Stevens agreed with the majority's conclusion, but maintained that there was no textual support for that decision in § 43(a). Instead the holding was the logical result of the gradual transformation of the meaning of § 43(a) by the Federal Courts, and was well supported by Congress's codification of these changes through recent amendments to the Act.⁶⁰

In light of the general consensus among the Courts of Appeals that have actually addressed the question, and the steps on the part of Congress to codify that consensus, stare decisis concerns persuade me to join the Court's conclusion that secondary meaning is not required to establish a trade dress violation under § 43(a) once inherent distinctiveness has been established.⁶¹

Justice Thomas also concurred with the judgment of the Court, but believed that the decision was well grounded in the common law, codified by Congress in § 43(a).⁶² Furthermore, he believed that the majority's analysis and interpretation of § 2, would lead to the misconstruction of that statute.⁶³ Justice Scalia filed a concurring statement stating that although he joined the opinion of the Court, he was in complete agreement with Justice Thomas's analy-

58. See Howard R. Popper, *A Tale of Tacos and Trade Dress*, NEW JERSEY L. J., August 17, 1992, at 14. "Prior to *Taco Cabana*, the doctrine had been applied. . . in *Jolly Good Industries, Inc. v. Elegra, Inc.*, 690 F.Supp. 227 (S.D.N.Y. 1988), but had been put into doubt by the Federal Circuit in. . . *Cicena Ltd. v. Colombia Telecommunications Group*, (CAFC 1990)." *Id.* According to the article, the doctrine was finally rejected by the Second Circuit in *Laureysens v. Idea Group, Inc.*, (May 15, 1992). "*Taco Cabana* would seem to overrule. . . *Cicena Ltd.*. . . as well as. . . *Laureysens*. . ." *Id.*

59. *Two Pesos*, 112 S.Ct. at 2759.

60. *Id.* at 2761-2766.

61. *Id.* at 2765.

62. *Id.* at 2766-67.

63. *Id.* at 2766.

sis which was complementary to the Majority's opinion.⁶⁴

CONCLUSION

Pursuant to this ruling, trade dresses enjoy the same protection as trademarks under § 43(a). Additionally, the Court removed registration as a prerequisite to protection under the Act, and replaced it with a registrability requirement. Hence, first the mark or dress must be registerable under § 2 by being either inherently distinctive or having attained a secondary meaning. Second, if registerable, the analysis shifts to § 43(a) and the mark or dress must be non-functional and unlikely to create confusion among the consuming public.

The Supreme Court aimed at giving effect to the legislative purposes behind the Act of preventing deception and unfair competition. Since both trade dress and trademarks perform the same source identifying function and achieve the purposes of the Act, protection of both under a uniform federal standard is necessary and logical. This decision provides a clear guideline as to exactly what kind of trade dress is protected for both new start-ups desiring to gain trade dress protection and competitors who would like to enter the market using a similar idea. There are no anti-competitive effects because if the dress is functional, descriptive, or generic, it will not be protected.

64. *Two Pesos*, 112 S.Ct. at 2761.

BOOK REVIEW

PATENT ALTERNATIVE DISPUTE RESOLUTION

PATENT ALTERNATIVE DISPUTE RESOLUTION HANDBOOK. By Tom Arnold with Michael G. Fletcher and Robert J. McAughan, Jr. *Clark Boardman Callaghan*, 1991. 140 pages, 2 appendices. \$85.00.

Nancy Yeend*

Alternative dispute resolution (ADR) has been used by commercial attorneys for many years to resolve conflicts without resorting to litigation. ADR processes, however, have been used for only slightly more than a decade to resolve patent disputes, as Tom Arnold points out in the Patent Alternative Dispute Resolution Handbook. There are many ADR processes that may be used to settle patent disputes, but this book fails to provide a comprehensive discussion of those processes. While the book provides a reasonably thorough analysis of arbitration in the patent area, it presents only elementary passages on mediation and minitrial with minor references to other ADR processes. For this reason, the title of the book is a misnomer and a more accurate title would have been "Patent Arbitration Handbook."

The writing style is informal, peppered with slang and colloquialisms typical of Arnold's Texas vernacular. The jaunty style begins in the Preface and is evident in Part One, but the colorful language fades as the book progresses.

The book is divided into three parts followed by two extensive appendices. Part Three consists of a single page that should have been incorporated elsewhere in the book. The pages of the book are separately numbered by chapter and the book is approximately 280 pages in length. The two appendices comprise fifty percent of the

Copyright © 1993 by Nancy Yeend.

* President, ADRA, Alternative Dispute Resolution Associates, Palo Alto, CA; ADR Instructor, San Francisco Law School.

book. Half of the remaining book is a single chapter on binding arbitration.

The text of the Patent Alternative Dispute Resolution Handbook, for the most part, is an expansion of Arnold's article, *Alternative Dispute Resolution in Intellectual Property Cases*.¹ He received an award in 1992 from the Center for Public Resources for an original article advancing the understanding in the field of ADR.² Unfortunately, the book does not maintain the tight writing style and consistent structure of the article.

Part One of the book is divided into five extremely short chapters covering the overburdened courts, evolution of ADR in patent law, and the increased use of ADR in general. Arnold describes the usual arguments in favor of ADR, including the chaos of the courts and the burdensome resource consumption of litigation, particularly the high expenditures of time and money. Arnold provides some compelling statistics, but his justification for use of ADR in patent law brings nothing new to the field. His arguments in favor of ADR are the same as those previous authors have raised in other areas of law.

The author's division of the evolution of ADR into three separate chapters is puzzling. The subdivision of a topic into multiple chapters seems unnecessary when a single chapter is little more than one page long. This chronic segmentation of subjects is perpetuated throughout the book.

The final chapter in Part One reviews the advantages of ADR. The issues discussed focus particularly on arbitration and delineate the customary advantages cited in all basic ADR texts: time, money, finality, expertise of a neutral, confidentiality, and preservation of relationships.

Part Two of the book contains sixteen chapters and promises, in its title, to address "Types of ADR Applied to Patent Disputes," leading the reader to expect a wide-ranging discussion of numerous ADR processes used in the patent law area. The result is disappointing. The chapter on arbitration represents more than fifty percent of the entire original text. Although not all the various forms of ADR have been used effectively to settle patent disputes, as Arnold accurately points out, the mere listing of ADR processes hardly warrants the title of "Patent Alternative Dispute Resolution Handbook."

1. Tom Arnold, *Alternative Dispute Resolution in Intellectual Property Cases*, 9 AIPLA SELECTED LEGAL PAPERS 1 (1991).

2. CPR Legal Program Award (1991).

Chapter 7, on binding arbitration, is one of two high points in the book. Here, Arnold articulates the basics of arbitration including agreements to adapt the process, discovery, enforceability, rules, and liquidated damages. Two complete discussions are presented in this chapter: arbitration law and international law.

The footnotes concerning current United States arbitration law are complete, and the points made regarding the Federal Rules of Civil Procedure as applied to arbitration are well worth reading. The discussion of international arbitration of intellectual property disputes is informative and offers readers a valuable summary of the international status of ADR by using examples from several countries.

The last half of the binding arbitration chapter embodies the primary value of this book: a nuts-and-bolts discussion of patent arbitration. Included are time-saving tips from one who obviously has experience with patent arbitration. He focuses on the special issues unique to patent disputes. Arnold and his associates discuss fundamental issues such as choice-of-law clauses, discovery, liquidated damages, injunctions, rules of evidence, and awards. Of significance is the discussion of issues surrounding the arbitrators themselves: selection, neutrality, and number. The author shines as he provides the ADR novice with a condensed course in arbitration.

There does not appear to be any readily identifiable taxonomic ordering to the series of chapters addressed in Part Two. More than a dozen ADR processes are introduced, but the discussion does not lead the reader along a clear, well-marked path. Processes could have been explained more effectively based on a continuum - from those providing the most control by the involved parties over the outcome to the least control, or grouped by binding versus non-binding or private versus court-annexed. It would be helpful for the attorney new to ADR to read a discussion of the various processes in some logical order. Taxonomic ordering allows relationships among the various processes to become apparent.

It is difficult to understand why Summary Jury Trial and Moderated Settlement Conference were not included in the "Court-Annexed ADR" chapter, particularly when both are court-annexed processes, and the presented discussion is minimal. Surprisingly, negotiation, the bread-and-butter ADR process for all attorneys, even patent law attorneys, is addressed by Arnold only in passing.

After arbitration the ADR processes of minitrial and mediation receive the most attention. The mediation chapter covers the

basics of the process and nearly half the chapter is spent on a trademark mediation example. This discussion closely parallels the text of the APLA article.³ Although the illustration is appropriate, mediation is such an important dispute resolution process, it is disappointing that this chapter was not more informative. This chapter describes "Requirements of Mediation" which, in fact, are not universal. For example, the mediator becoming a fact-finder may be a violation of the code of ethics in some states.⁴ As with any generic text, state rules may contradict broad statements and the author should make appropriate qualifications.

The portion of the chapter covering the rudimentary aspects of one type of minitrial is adequate. While Arnold, throughout the book, decries the lack of consistency in the definitions of ADR terms, he refers to minitrial as an *arbitration* hybrid. Most ADR writers consider the minitrial a *mediation* hybrid⁵ because of the non-binding nature of the minitrial. The reasons given pro and con for this process are not unique to minitrial, but are consistent with all non-binding processes.

The second high point of the book is the appendices: Appendix A, "Rules of Arbitration" and Appendix B, "Patent ADR Materials." Appendix A comprises nearly eighty percent of the appendices and consists of reprints of arbitration rules from seven different national and international organizations which administer the arbitration process. As a repository for this collection of rules, Appendix A may function as a ready reference for comparison of the various arbitration rules. These rules are time-dated and so their value is limited.

Appendix B1 includes a sample ADR agreement which incorporates a two-step process for resolving disputes: minitrial followed by mediation. The rationale for this suggested sequence appears to be Arnold's contention that although foreign courts frown on arbitration of patent disputes, they do not seem concerned about settlement processes when decisions are reached through negotiation. The only shortcoming of this section is a lack of discussion of the issue of finding amicable parties to a lawsuit who are willing to calmly discuss an ADR contract. To his credit, in earlier chapters, Arnold encourages incorporation of ADR in contracts between par-

3. Arnold, *supra* note 1.

4. See, e.g., Florida Rules of Civil Procedure, §§ 10.010-10.290.

5. See, e.g., Green, Marks, & Olson, *Settling Large Case Litigation: An Alternative Approach*, 11 LOY. L.A. L. REV. 493 (1978); also see YAROSLAV SOCHYNSKY & MARIAN BAIRD, CALIFORNIA ADR PRACTICE GUIDE, fig. 31-2 at 31-7 (forthcoming 1992).

ties during their initial transactions as a mechanism to constructively manage conflict before a dispute escalates.

The pearl in this book is Appendix B2, "Mediation Outline." The twenty-one pages are a quick course on how to be a mediator. These pages provide a detailed outline of the stages of the mediation process and the techniques available to the mediator. Although not intended as a "how-to" course, this section of the book provides a road map for those who desire a better understanding of the process so they can anticipate and prepare for more effective representation of their clients. The page of verbatim text from the book *Getting to Yes*,⁶ however, was a distraction.

The binding arbitration chapter and the listing of arbitration rules make Arnold's work a basic arbitration handbook. The outline of the mediation process in the appendix is a concise primer. The book in general has significant weaknesses in format, structure, and content. On balance, Arnold's earlier article⁷ delivers as much substance as the text in this book and is more enjoyable reading.

6. ROGER FISHER & WILLIAM URY, *GETTING TO YES* (1981).

7. Arnold, *supra* note 1.

